Anthony J. Davis, Esq. (#033811992) (adavis@ogcsolutions.com)
Brian E. Moffitt, Esq. (#020831992) (bmoffitt@ogcsolutions.com)
SANTOMASSIMO DAVIS LLP
1 Gatehall Drive, Suite 100
Parsippany, New Jersey 07054
(201) 712-1616
Attorneys for Plaintiffs

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MSP RECOVERY CLAIMS, SERIES LLC.; MSPA CLAIMS 1, LLC; MAO-MSO RECOVERY II, LLC, SERIES PMPI, a segregated series of MAO-MSO RECOVERY II, LLC; MSP RECOVERY CLAIMS SERIES 44, LLC, MSP RECOVERY CLAIMS PROV, SERIES LLC, and MSP RECOVERY CLAIMS CAID, SERIES LLC, PLAINTIFFS, VS. CELGENE CORPORATION AND BRISTOL-MYERS SQUIBB COMPANY, DEFENDANTS.	Civil Action No. ___:21-cv-_____ **COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiffs MSP Recovery Claims, Series LLC, MSPA Claims 1, LLC and MAO-MSO Recovery II, LLC, Series PMPI, a segregated series of MAO-MSO Recovery II, LLC, MSP Recovery Series 44, LLC, MSP Recovery Claims PROV, Series LLC, and MSP Recovery Claims CAID, Series LLC (collectively referred to as "Plaintiffs" or "MSP" unless otherwise specifically identified hereby), through its attorneys, Santomassimo Davis LLP, by way of Complaint against Defendant Celgene Corporation ("Celgene") and Defendant Bristol-Myers Squibb Company ("Bristol-Myers Squibb") (collectively referred to as "Defendants") state as follows:

I. NATURE OF THE CASE

1. Plaintiffs bring this action against Celgene and its parent Bristol-Myers Squibb for violations of consumer protection and common law claims, arising out of Celgene's anticompetitive scheme that has prevented generic brands from entering the market to compete with Celgene's high-priced drugs Thalomid and Revlimid. The improper actions described below have allowed Celgene to maintain supracompetitive prices that thwart legitimate competition that would have benefited consumers and the public at large by drastically lowering the price of these medically necessary drugs. Celgene's misconduct is a textbook example of the type that is proscribed by both federal and state law and is emblematic of the historic and unprecedented increase in pharmaceutical drug costs. Plaintiffs' allegations are made on personal knowledge as to Plaintiffs, publicly available information and upon information and belief as to all other matters.

2. The subject drug Thalomid was originally developed, marketed, and sold under the brand name Thalidomide in the late 1950s and early 1960s as a sedative and anti-nausea medication. Thalidomide had catastrophic results "[w]hen taken by pregnant women for morning sickness, it caused missing limb parts in the fetus . . . as well as organ damage and death. Fifty years after the drug's heyday, the fear it inspired haunts arguments about the safety and regulation of medications . . . That tragedy is a major reason the Food and Drug Administration has as much authority over new drugs as it does today."[1]

3. In 1998, Celgene obtained U.S. Food and Drug Administration ("FDA") approval to market Thalomid® (thalidomide) for a leprosy complication known as erythema nodosum leprosum ("ENL").

4. In 2005, Celgene successfully developed a thalidomide analog, Revlimid® (lenalidomide), and obtained FDA approval to market it for a specific chromosomal variant of

[1] Amanda Schaffer, *Thalidomide's Comeback*, Slate, Jan. 10, 2011, http://www.slate.com/articles/double_x/doublex/2011/01/thalidomides_comeback.html.

myelodysplastic syndromes ("MDS"). Celgene would go on to obtain FDA approvals for additional Revlimid indications, including for a subset of multiple myeloma ("MM") patients in 2006,[2] and later for a subset of mantle cell lymphoma ("MCL") patients in 2013.

5. However, unsatisfied with profits earned within the pharmaceutical legal and regulatory framework, Celgene commenced an anticompetitive scheme to illegally monopolize the market for Thalomid an Revlimid. Celgene constructed an impenetrable monopolistic fortress and engaged in a multi-prong scheme to unlawfully maintain an 100% share of the market for these two drugs by successfully interfering with competitors' efforts to develop and/or obtain FDA approval for generic versions of Thalomid and/or Revlimid at each progressive step of development.

6. As part of this anticompetitive scheme, plaintiffs allege that Celgene is: (1) manipulated the safety program designed to protect patients from thalidomide's and lenalidomide's teratogenic properties; (2) prevented pharmacies and ingredient suppliers from acting as alternative sources of samples for such would-be generic competitors; (3) fraudulently obtained various patents from the U.S. Patent and Trademark Office ("USPTO") for Thalomid and Revlimid and their associated safety distribution protocols; (4) serially commencing "sham" patent infringement lawsuits; and (5) filed baseless citizen petitions with the FDA to stymie generic approvals.

7. In the rare instances where Celgene's efforts failed to prevent a would-be competitor from prosecuting an Abbreviated New Drug Application ("ANDA"), and FDA approval of an ANDA for a generic version of Revlimid or Thalomid became possible, Celgene entered into confidential

[2] Under the FDA's orphan drug exclusivity program, 21 U.S.C. §§ 360aa-cc, the FDA may not approve a generic equivalent for a specific indication or "rare disease" that a brand drug is FDA-approved to treat for a period of seven (7) years. MM is such a "rare disease." Therefore, until May 25, 2013, the FDA could not approve a generic thalidomide for the treatment of MM. It could, nevertheless, approve generic thalidomide for the treatment of other indications. This is known as a "skinny label."

settlements with its competitors that, upon information and belief, included anti-competitive "pay-for-delay" reverse payments. The federal government has routinely criticized – and challenged in court – the same sort of anticompetitive practices in which Celgene engages.[3]

8. In 2006, a month's supply of Revlimid cost $6,195.[4] In 2010, the price was about $8,000 for a one-month supply. Now, a twenty-eight (28) day supply of Revlimid costs patients and their health insurers as much as $20,000, and a twenty-eight (28) day supply of Thalomid costs them as much as $10,000. In 2016, Celgene's total revenue was $11.23 billion, of which $6.97 billion was from Revlimid and $152.10 million was from Thalomid. When Thalomid first entered the market, it cost approximately $6 per capsule. In 2014, its price soared to as much as $357 per capsule.

9. In the last ten (10) years, as a result of Celgene's anticompetitive conduct to eliminate/limit generic alternatives from the market, Celgene has been able to routinely increase its prices either once or twice per year.

10. Celgene's illicit and monopolistic efforts with respect to Thalomid and Revlimid have been enormously profitable. Between 2006 and 2016, Celgene recorded $35.60 billion of Revlimid sales and $3.65 billion of Thalomid sales, yielding the following respective annual sales:[5]

	2016	2015	2014	2013	2012	2011	2010	2009	2008	2007
Revlimid	6974M	5800M	4980M	4280M	3770M	3210M	2470M	1706M	1325M	774M	321M

[3] *See, e.g.*, Federal Trade Commission, *Pay for Delay: How Drug Company Pay-Offs Cost Consumers Billions* (Jan. 2010), https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.

[4] Alison Kodjak, *How A Drugmaker Gamed The System to Keep Generic Competition Away* (May 17, 2018), https://www.npr.org/sections/health-shots/2018/05/17/571986468/how-a-drugmaker-gamed-the-system-to-keep-generic-competition-away.

[5] Net product sales figures drawn from Celgene's Annual Reports/Form 10-K filings for fiscal years ending 2007-2016.

Thalomid	152M	185M	221M	245M	302M	339M	387M	437M	505M	447M

11. In December 2016, Revlimid was the second-highest grossing drug worldwide.[6] For the year ended December 31, 2020, Bristol-Myers Squibb reported that Revlimid revenue had grown to more than $12.1 billion worldwide, including more than $8.29 billion in the United States.[7]

12. There has never been a generic substitute for Revlimid or Thalomid available in the U.S., enabling Celgene to price the drugs at levels unrestrained by generic competition.

13. Celgene's anticompetitive tactics to block generic entry have caused Plaintiffs to pay supracompetitive prices for these drugs in violation of various federal antitrust laws, states' antitrust, consumer protection, trade practices, and insurance fraud laws.

14. Plaintiffs seek to recover incurred civil damages and over payments made on behalf of their Assignors who purchased or otherwise provided reimbursement for Thalomid and/or Revlimid, which was prescribed and dispensed to Plaintiffs' Assignors' Enrollees as well as injunctive relief.

II. JURISDICTION AND VENUE

15. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1337 as well as 15 U.S.C. §§ 15 and 26. Plaintiffs assert federal claims for treble damages, injunctive relief and costs of suit, including reasonable attorneys' fees, against Defendants under Section 2 of the Sherman Act, 15 U.S.C. § 2, and Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26.

[6] Amy Brown, *EP Vantage 2017 Preview* (Dec. 2016), http://info.evaluategroup.com/rs/607-YGS-364/images/EPV2017Prev.pdf.

[7] https://news.bms.com/news/details/2021/Bristol-Myers-Squibb-Reports-Fourth-Quarter-and-Full-Year-Financial-Results-for-2020/default.aspx.

16. This Court has supplemental jurisdiction over Plaintiffs' pendent state law claims pursuant to 28 U.S.C. § 1367, as the state law claims are so related as to form part of the same case or controversy. Such supplemental or pendent jurisdiction will also avoid unnecessary duplication and multiplicity of actions, and should be exercised in the interests of judicial economy, convenience and fairness.

17. This Court has personal jurisdiction over Defendants because they purposefully directed their business activities toward this jurisdiction and has substantial contacts with this jurisdiction, and because Plaintiffs' claims for relief arise from and relate to illegal acts committed by Defendants within this jurisdiction.

18. Venue is appropriate within this district because Defendants transact business within this district, have agents and can be found in this district, and the cause of action or some part thereof arose in this district. Venue is also appropriate within this district under Section 12 of the Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. §§ 1391(b) and (c).

III. PARTIES

19. Plaintiff, MSP Recovery Claims, Series LLC ("MSPRC"), is a Delaware limited liability company with its principal place of business located at 2701 S. Le Jeune Rd., Coral Gables, Florida 33134. MSPRC's limited liability company agreement provides for the establishment of one or more designated series. MSPRC has established various designated series pursuant to Delaware law in order to maintain various claims recovery assignments separate from other Company assets, and in order to account for and associate certain assets with certain particular series. Pursuant to MSPRC's limited liability agreement, all designated series form a part of MSPRC. MSPRC may receive assignments in the name of MSPRC and further associate such assignments with a particular series or may have claims assigned directly to a particular series. In either event, MSPRC will maintain the right to sue on behalf of each series and pursue any and

all rights, benefits, and causes of action arising from assignments to a series. Any claim or suit may be brought by MSPRC in its own name or it may elect to bring suit in the name of its designated series. MSPRC's limited liability agreement provides that any rights and benefits arising from assignments to its series shall belong to MSPRC. Certain series of this Plaintiff has been assigned the right to assert the causes of action alleged in this Complaint from numerous Health Maintenance Organizations, first-tier, downstream and related entities that provide health care coverage and benefits, including prescription drug coverage ("Health Plans") to its beneficiaries ("Enrollees"). Because of the assignment, or assignments, Plaintiff, through its operating agreement, has been authorized and is empowered to bring this action to recover the cost of payments for Thalomid and Revlimid made on behalf of the Assignors' Enrollees for which Defendants are liable. Plaintiff's assignments, samples of which are alleged in detail in the Appendix to this Complaint, are valid and binding contracts.

20. Plaintiff, MSPA Claims 1, LLC, is a Florida limited liability company, with its principal place of business located at 2701 S. Le Jeune Rd., Coral Gables, Florida 33134. One or more Health Plans irrevocably assigned to this Plaintiff the right to assert the causes of action alleged in this Complaint. Because of the assignment, or assignments, Plaintiff has been authorized and is empowered to bring this action to recover the cost of payments for Thalomid and Revlimid made on behalf of the Assignors' Enrollees for which Defendants are liable. Plaintiff's assignments, samples of which are alleged in detail in the Appendix to this Complaint, are valid and binding contracts.

21. Plaintiff, MAO-MSO Recovery II, LLC, Series PMPI, a segregated series of MAO-MSO Recovery II, LLC, is a Delaware limited liability company with its principal place of business at 45 Legion Drive, Cresskill, New Jersey 07626. One or more Health Plans irrevocably assigned to this Plaintiff the right to assert the causes of action alleged in this Complaint. Because of the assignment, or assignments, Plaintiff has been authorized and is empowered to bring this

action to recover the cost of payments for Thalomid and Revlimid made on behalf of the Assignors' Enrollees for which Defendants are liable. Plaintiff's assignments, samples of which are alleged in detail in the Appendix to this Complaint, are valid and binding contracts.

22. Plaintiff, MSP Recovery Claims Series 44, LLC ("Series 44") is a duly organized and existing Delaware series limited liability company with its principal place of business located in Coral Gables, Florida. Series 44's limited liability company operating agreement provides for the establishment of one or more designated series as permitted by Delaware law. Del. Code Ann. Tit. 6, § 18-215(a). Accordingly, Series 44 established various designated series to serve as units of the company for the purpose of maintaining various claims recovery assignments separate from other company assets, and in order to account for and associate certain assets with certain particular series. Series 44 has enumerated rights relating to its designated series pursuant to its limited liability agreement and consistent with Delaware law. Del. Code Ann. Tit. 6, §§ 18-215(a)-(c). Specifically, all rights and benefits arising from assignments to its series shall belong to Series 44. Series 44 may receive assignments in the name of Series 44 and further associate such assignments with a particular series or may have claims assigned directly to a particular series. In either event, Series 44 and the designated series are authorized to pursue or assert any claim or suit capable of being asserted by any designated series arising from, or by virtue of, an assignment to a designated series. Series 44 retains the legal right to sue on behalf of each designated series and pursue all rights, benefits, and causes of action arising from assignments to a series in its own name or in the name of the designated series. One or more Health Plans irrevocably assigned to certain series of this Plaintiff the right to assert the causes of action alleged in this Complaint. Because of the assignment, or assignments, Plaintiff, through its operating agreement, has been authorized and is empowered to bring this action to recover the cost of payments for Thalomid and Revlimid made on behalf of the Assignors' Enrollees for which Defendants are liable. Plaintiff's assignments,

samples of which are alleged in detail in the Appendix to this Complaint, are valid and binding contracts.

23. Plaintiff, MSP Recovery Claims PROV, Series LLC ("Claims PROV") is a duly organized and existing Delaware series limited liability company with its principal place of business located in Coral Gables, Florida. Claims PROV's limited liability company operating agreement provides for the establishment of one or more designated series as permitted by Delaware law. Del. Code Ann. Tit. 6, § 18-215(a). Accordingly, Claims PROV established various designated series to serve as units of the company for the purpose of maintaining various claims recovery assignments separate from other company assets, and in order to account for and associate certain assets with certain particular series. Claims PROV has enumerated rights relating to its designated series pursuant to its limited liability agreement and consistent with Delaware law. Del. Code Ann. Tit. 6, §§ 18-215(a)-(c). Specifically, all rights and benefits arising from assignments to its series shall belong to Claims PROV. Claims PROV may receive assignments in the name of Claims PROV and further associate such assignments with a particular series or may have claims assigned directly to a particular series. In either event, Claims PROV and the designated series are authorized to pursue or assert any claim or suit capable of being asserted by any designated series arising from, or by virtue of, an assignment to a designated series. Claims PROV retains the legal right to sue on behalf of each designated series and pursue all rights, benefits, and causes of action arising from assignments to a series in its own name or in the name of the designated series. One or more Health Plans irrevocably assigned to certain series of this Plaintiff the right to assert the causes of action alleged in this Complaint. Because of the assignment, or assignments, Plaintiff, through its operating agreement, has been authorized and is empowered to bring this action to recover the cost of payments for Thalomid and Revlimid made on behalf of the Assignors' Enrollees for which Defendants are liable. Plaintiff's assignments, samples of which are alleged in detail in the Appendix to this Complaint, are valid and binding contracts.

24. Plaintiff, MSP Recovery Claims CAID, Series LLC ("Claims CAID") is a duly organized and existing Delaware series limited liability company with its principal place of business located in Coral Gables, Florida. Claims CAID's limited liability company operating agreement provides for the establishment of one or more designated series as permitted by Delaware law. Del. Code Ann. Tit. 6, § 18-215(a). Accordingly, Claims CAID established various designated series to serve as units of the company for the purpose of maintaining various claims recovery assignments separate from other company assets, and in order to account for and associate certain assets with certain particular series. Claims CAID has enumerated rights relating to its designated series pursuant to its limited liability agreement and consistent with Delaware law. Del. Code Ann. Tit. 6, §§ 18-215(a)-(c). Specifically, all rights and benefits arising from assignments to its series shall belong to Claims CAID. Claims CAID may receive assignments in the name of Claims CAID and further associate such assignments with a particular series or may have claims assigned directly to a particular series. In either event, Claims CAID and the designated series are authorized to pursue or assert any claim or suit capable of being asserted by any designated series arising from, or by virtue of, an assignment to a designated series. Claims CAID retains the legal right to sue on behalf of each designated series and pursue all rights, benefits, and causes of action arising from assignments to a series in its own name or in the name of the designated series. One or more Health Plans irrevocably assigned to certain series of this Plaintiff the right to assert the causes of action alleged in this Complaint. Because of the assignment, or assignments, Plaintiff, through its operating agreement, has been authorized and is empowered to bring this action to recover the cost of payments for Thalomid and Revlimid made on behalf of the Assignors' Enrollees for which Defendants are liable. Plaintiff's assignments, samples of which are alleged in detail in the Appendix to this Complaint, are valid and binding contracts

25. Plaintiffs' Assignors provide health benefits to their Enrollees, who reside throughout the United States. As third-party payers of pharmaceutical claims for their enrollees,

Plaintiffs' Assignors are end payers for their Enrollees' Thalomid and Revlimid prescriptions and are thereby injured as a result of Celgene's unlawful behavior. Plaintiffs' Assignors' data confirms that during the relevant time period they have indirectly purchased and/or provided reimbursement for Thalomid and Revlimid throughout the United States. When a generic version of a prescription drug is available, Plaintiffs' Assignors' Enrollees – and Plaintiffs' Assignors – typically purchase and/or provide reimbursement for the generic version. Because Celgene has restricted the ability of generics to enter the market, Plaintiffs' Assignors have purchased and/or provided reimbursements for Thalomid and Revlimid at anticompetitive price levels. Plaintiffs are pursuing recovery related to those overpayments.

26. Plaintiffs' Assignors provide health insurance coverage and benefits, including prescription drug coverage, to individual beneficiaries subscribed to their plans *i.e.*, Enrollees.

27. Plaintiffs' Assignors provided payment for their Enrollees' prescriptions for Thalomid and Revlimid.

28. Defendant Celgene is a drug manufacturer, incorporated in Delaware and headquartered at 86 Morris Avenue, Summit, New Jersey. It is publicly traded under the NASDAQ symbol "CELG." Celgene manufactures, markets, and sells Thalomid and Revlimid.

29. Defendant Bristol-Myers Squibb wholly owns Celgene as its subsidiary, having acquired Celgene pursuant to a January 2, 2019 merger agreement.

30. Defendant Bristol-Myers Squibb is a biopharmaceutical drug company incorporated under the laws of Delaware with its principal executive offices located at 430 East 29th Street, 14th Floor, New York, New York 10016. Bristol-Myers Squibb is a publicly traded corporation registered on the New York Stock Exchange under the trading symbol "BMY."

IV. ECONOMIC BACKGROUND

31. Due to laws that regulate marketing/selling, prescribing, and filling prescription drugs, the United States is a fertile venue ripe for illegal anticompetitive exploitation by drug manufacturers who seek to profit from product monopolies.

32. For most consumer products, the person responsible for paying for them is also the person selecting them. The pharmaceutical marketplace departs from this norm.

33. Prescription drugs may only be dispensed pursuant to a doctor's prescription, and a licensed pharmacist may dispense only the brand-name drug named in the prescription or its AB-rated, FDA-approved generic equivalent.[8]

34. In most instances, the patient and his health insurer pay for the prescription drug that a doctor has prescribed. Like the pharmacist, their "choice" is limited to the drug named in the prescription or its AB-rated generic equivalent. Therefore, the doctor's prescription defines the relevant product market because it limits the patients' (and pharmacist's) choice to the drug named therein.

35. When there is no generic competition for a brand-name drug, the brand manufacturers can set and maintain prices without losing market share. The ability to do this is the result of the brand-name drug company's monopoly power over the market for that drug in both its brand-name and generic form. When an AB-rated generic is available, price is reintroduced to the product selection decision at the pharmacy counter, and the disconnect between choice and payment is lessened, disabling the brand manufacturer from exploiting that disconnect. Generic introduction restores normal competitive pressures.

[8] In many states, pharmacists must substitute an AB-rated generic for a brand-name drug without seeking permission from the prescribing doctor.

36. Typically, AB-rated generic versions of brand-name drugs are priced significantly below their brand-name counterparts. When multiple generic manufacturers enter the market, prices for generic versions of a brand-name drug predictably decrease, sometimes as much as by 90%, because of price competition among generic manufacturers.[9] The FDA reports that, in 2010, the use of FDA-approved generics saved $158 billion, or $3 billion per week, and that one year after entry, a generic drug takes over 90% of the corresponding brand-name drug's sales at 15% of the price. Generic drug entry, therefore, is a huge threat to the continued profitability of a branded drug.

37. As the price gap between the brand-name drug and its corresponding generic drug widens, the former's sale's volume shrinks. Price is the only material difference between a brand-name drug and its AB-rated generic equivalent.

38. For every rung in the prescription drug ladder, except for the brand-name drug manufacturer, there is a financial benefit to choose the generic drug, specifically: (1) pharmacies normally earn a higher markup on generic drugs because of pricing structure and federal reimbursement rules; (2) private health insurers typically offer incentives to pharmacies to fill prescriptions with generics; and (3) to incentivize patients to request generic drugs, health insurers often offer lower copays for generic drugs than for brand-name drugs.

39. Generic competition enables purchasers like Plaintiffs' Assignors to purchase a generic version of a brand-name drug at substantially lower prices. However, until generic manufacturers enter the market with an AB-rated generic, there is no generic drug which competes effectively with the brand-name drug, and therefore, the brand-name manufacturer can continue

[9] *See, e.g.*, Jon Leibowitz, *"Pay for Delay" Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers' Wallets, and Help Pay for Health Care Reform* (June 23, 2009), http://www.ftc.gov/sites/default/files/documents/public_statements/pay-delay-settlements- pharmaceutical-industry-how-congress-can-stop-anticompetitive-conduct-protect/090623payfordelayspeech.pdf.

to charge supracompetitive prices without losing sales. Given their acute knowledge of the effects of generic entry into a market, brand-name manufacturers like Celgene have a strong incentive to delay the entry of a generic drug onto the market, including by entering illegal reverse "pay for delay" settlement agreements and serially filing frivolous patent infringement lawsuits, among other anticompetitive tactics.

V. THE REGULATORY BACKGROUND

a. The Hatch-Waxman Act and NDA Approval Process

40. Under the Federal Food, Drug and Cosmetics Act (21 U.S.C. §§ 301-392) ("FDCA"), a manufacturer that creates a new, pioneer drug must obtain the approval of the FDA to sell the new drug by filing a New Drug Application ("NDA"). An NDA must include submission of specific data concerning the safety and efficacy of the drug and identify any patents claiming the drug. 21 U.S.C. § 355(b).

41. When the FDA approves a brand-name manufacturer's NDA, it lists in a publication entitled the "Approved Drug Products with Therapeutic Equivalence Evaluations" (known as the "Orange Book") any patents which, according to the information the brand-name manufacturer supplies to the FDA: (1) claim the approved drug or its approved uses; and (2) for which a "claim of patent infringement could reasonably be asserted if a person is not licensed by the owner engaged in the manufacture, use, or sale of the drug."[10]

42. The FDA does not investigate the patents or verify the NDA sponsor's representations for accuracy or trustworthiness prior to listing patents in the Orange Book. It is a pure administrative and clerical act.

[10] 21 U.S.C. § 355(b)(1); 21 U.S.C. § 355(g)(7)(A)(iii).

43. Once a brand manufacturer lists a patent in the Orange Book, it puts potential generic competitors on notice that the brand manufacturer considers the patent to cover its drug.

b. The Hatch-Waxman Act and ANDA Approval Process

44. In 1984, Congress amended the FDCA with the enactment of the Hatch-Waxman Act ("Hatch-Waxman").[11] Congress' principal intent was for Hatch-Waxman to simplify and reduce the regulatory hurdles for prospective generic manufacturers, by replacing the lengthy and costly NDA approval process with an expedited ANDA review process.[12] Under Hatch-Waxman, an ANDA applicant may rely on the safety and efficacy findings of the NDA for the referenced brand-name drug, if the ANDA demonstrates the proposed generic drug is therapeutically equivalent and "bioequivalent," ("BE") *i.e.*, it contains the same active ingredient(s), dosage form, route of administration, and strength as the brand-name drug, and is absorbed at the same rate, and to the same extent, as the brand-name drug. For ANDAs that pass this test, the FDA assigns an "AB" rating to the generic drug.

45. BE is generally demonstrated via studies in which the proposed generic is compared to the Reference Listed Drug ("RLD," which is, in this instance, the brand-name drug) in either *in vivo* or *in vitro* studies.[13] These studies require the ANDA applicant to have access to sufficient samples of the RLD to conduct the necessary comparisons. Without RLD samples, it is impossible to complete and file an ANDA application.

46. The FDA illuminates the issue:

> To obtain approval for a generic drug, the generic company needs to show, among other things, that its version of the product is bioequivalent to the RLD [i.e. the

[11] Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman").

[12] *Id.*

[13] *In vivo* studies are studies conducted on live subjects. *In vitro* studies are conducted in a laboratory.

> brand drug, or reference listed drug]. This usually requires the generic company to conduct bioequivalence studies comparing its product to the RLD, and to retain samples of the RLD used in testing after a study is complete. To conduct these kinds of bioequivalence studies, the generic company needs to obtain samples (generally between 1,500 and 5,000 units) of the RLD.[14]

47. Only samples of the RLD approved by the FDA and marketed in the United States may be used for BE testing purposes. In the ordinary course, a prospective ANDA sponsor obtains samples by buying them, at market price, from a drug wholesaler or distributor. Wholesalers and distributors are large companies that buy drugs from manufacturers for the purpose of re-selling them to pharmacies or other entities. Generic companies are authorized to buy prescription drugs from distributors for BE testing purposes.

48. However, given the nature of the subject drugs, Celgene's own former senior vice president of global regulatory affairs, drug safety, risk management, and quality assurance Graham Burton testified that Celgene is the only source from which a generic company could obtain Thalomid or Revlimid for purposes of BE testing.[15]

c. The Hatch-Waxman's Balancing Act

49. As a counterbalance to Hatch-Waxman's simplified ANDA process, Hatch-Waxman also provides brand manufacturers with the ability, merely by filing a patent infringement lawsuit, to easily obtain what is essentially a preliminary injunction, in the form of an automatic stay of up to thirty (30) months of the FDA's ability to approve a generic manufacturer's ANDA.

---

[14] FDA, *Reference Listed Drug (RLD) Access Inquiries*, https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm607738.htm (last visited Feb. 26, 2019).

[15] Exhibit to Brief in Opposition to Motion for Summary Judgment, *Mylan Pharmaceuticals, Inc. v. Celgene Corp.*, No. 2:14-cv-02094-ES-MAH (D.N.J. Mar. 20, 2018) ("MSJ Opp."), Dkt. No. 285-15 at 69-70.

50. To obtain FDA approval of an ANDA, the generic manufacturer must certify that it will infringe no patent listed in the Orange Book claiming the brand drug, because either:

a. No patent for the brand-name drug has been filed with the FDA (a "Paragraph I Certification");
b. The patent for the brand-name drug has expired (a "Paragraph II Certification");
c. The patent for the brand-name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III Certification"); or
d. The patent for the brand-name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV Certification").[16]

51. When a generic manufacturer files a Paragraph IV Certification, it must notify the brand manufacturer and patent owner. The ANDA filing itself becomes an artificial act of patent infringement, entitling the patent holder to sue for injunctive relief, according to Hatch-Waxman.

52. If the patent holder sues the ANDA filer within forty-five (45) days of receiving the Paragraph IV Certification, Hatch-Waxman prevents the FDA from granting final approval to the ANDA until the earlier of (a) thirty (30) months after the lawsuit is commenced, or (b) the court presiding over the patent infringement action rules that the patent is invalid or not infringed by the ANDA.[17] It is almost always the case that the thirty (30) months expire before the court rules, resulting in a 30-month statutory stay.

53. However, during the 30-month stay, the FDA may grant "tentative approval" to an ANDA applicant if the agency determines that the ANDA would qualify for final approval, but for the 30-month stay.

54. Hatch-Waxman grants a 180-day period of market exclusivity to the first Paragraph IV ANDA applicant ("first filer") to file a substantially complete ANDA. During the 180-day

[16] 21 U.S.C. § 355(g)(2)(A)(vii).

[17] 21 U.S.C. § 355(j)(5)(B)(iii).

exclusivity period (measured from the first commercial marketing of the generic drug or the date of a court decision finding the listed patent invalid, unenforceable, or not infringed[18]), the first ANDA filer enjoys 180 days of freedom from competition from other generic versions of the drug, and during that period can capture almost all of the market for the drug while selling the generic for a higher price than the market will support once additional generics enter the market.

55. The Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA") set forth numerous conditions under which a first filer forfeits its 180-day exclusivity, thereby allowing other ANDA filers to enter the market.[19] For example, forfeiture occurs if the first filer fails to obtain tentative approval within thirty (30) months from filing, unless the failure is caused by a change in, or review of, the approval requirements.

56. Under the "Agreement with another applicant" provision, the first filer will forfeit its exclusivity if it "enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the [Paragraph IV certification] …."[20]

57. Under the "failure to market" provision, a first filer forfeits its 180-day exclusivity if it fails to market its generic drug by the *later of*:

> (a) *the earlier* of the date that is
> (1) 75 days after receiving final FDA approval; or
> (2) 30 months after the date it submitted its ANDA; or
> (b) the date that is 75 days after the date as of which, as to each of the patents qualifying the first applicant for exclusivity (i.e., as to each patent for which the first applicant submitted a Paragraph IV certification), at least one of the following has occurred
> (1) a final decision of invalidity or non-infringement;

[18] 21 U.S.C. § 355(j)(5)(B)(iv)); *see also* 21 C.F.R. § 314.107(c)(1)).

[19] Public Law 108-173; 21 U.S.C. A. § 355(j)(5)(D).

[20] 21 U.S.C. § 355(j)(5)(D)(i)(V).

> (2) a settlement order entering final judgment including a finding the patent is invalid or not infringed; or
> (3) the NDA holder delists the patent from the Orange Book.[21]

58. Branded-manufacturers and first filers can structure an agreement to circumvent the above provisions and keep the 180-day exclusivity in place by, among other things, settling their litigation before a final judgment of invalidity or non-infringement can be entered, or by seeking a consent judgment that does not include a finding that all the patents for which the first filer submitted a Paragraph IV Certification were invalid or not infringed. Consequently, a subsequent ANDA filer can fight this only by obtaining a judgment that all patents for which the first filer filed a Paragraph IV Certification are invalid or not infringed, thereby triggering forfeiture of the first filer's 180-day exclusivity rights.

d. The REMS Programs

59. Since at least the 1960s, the FDA has examined and implemented various methods for managing risks related to pharmaceutical products. Methods have included disclosure and labelling requirements. The Controlled Substance Act of 1970 regulated manufacturers, prescribers, dispensers, and labels and permitted the FDA to require warnings on packages.[22]

60. In the 1990s, the FDA began to work with manufacturers to develop risk management programs for drugs with dangerous side effects. Then, in the 2000s, the FDA established Risk Minimization Action Plans ("RiskMAPs"), in which manufacturers voluntarily instituted risk minimizing plans.

61. In 2007, Congress passed the Food and Drug Administration Amendments Act ("FDAAA"), which codified the Risk Evaluation and Mitigation Strategies ("REMS") to be implemented with respect to certain pharmaceutical products "that have already been approved"

[21] 21 U.S.C. § 355(j)(5)(D)(i)(I).

[22] 21 U.S.C. § 801 *et seq.* (2002).

and directs the Secretary of Health and Human Services ("HHS") to establish an active post-market drug surveillance infrastructure.[23]

62. A REMS can include, *inter alia*, a medication guide, patient package inserts, and/or restrictions on the distribution of the drug.

63. Since their enactment in 2007, REMS have been increasingly common in the FDA approval process; roughly 40% of new drugs have REMS programs.

64. REMS are intended to give the FDA authority to condition drug approval on the implementation of a program designed to address serious risks associated with certain pharmaceutical products. The intention is not to make drugs, or drug samples, less available. In fact, §505-1(f)(8) explicitly prohibits brand manufacturers from using REMS to "block or delay approval of" an ANDA. The FDAAA does not prohibit the sale of REMS-subject drugs to generic manufacturers that will use those drugs in controlled BE testing, nor does it give an NDA holder the right to interfere with a competitors' ability to purchase necessary drug samples.

e. Brand Manufactures Have Abused REMS to Block Generic Competition

65. Competition from generics dramatically reduces a brand manufacturer's profits as prices erode and the brand loses market share. Brand manufacturers are therefore highly motivated to delay or block generic entry by extending their monopoly beyond its legal limits. Brand manufacturers have come to do this through, *inter alia*, abusing and "gaming" REMS programs.

66. In 2016, Janet Woodcock, Director of FDA's Center for Drug Evaluation and Research ("CDER") testified that brand companies use REMS programs "as an excuse to not give the drug to the generics so they can compare it to their drug." This behavior, she noted, causes "barriers and delays in getting generics on the market."[24]

[23] 21 U.S.C. § 355-1(f)(8).
[24] *Generic Drug User Fee Amendments: Accelerating Patient Access to Generic Drugs: Hearing Before the S. Comm. on Health, Educ., Labor & Pensions*, 114th Cong. 31 (2016) (testimony of Janet Woodcock, Director, Center for Drug Evaluation & Research).

f. State and Federal Governments Recognize the Anticompetitive Harm of REMS Abuse and Targeted REMS Abuse

67. REMS abuse has come under increasing scrutiny as generics' resulting inability to enter the market has caused real and substantial harm to the American public by increasing U.S. healthcare costs by more than $5 billion annually.[25]

68. In June 2016, the Senate Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights, held a hearing on a bill entitled "Creating and Restoring Equal Access to Equivalent Samples Act of 2016" ("CREATES Act"). The bill proposed creating an independent cause of action for refusal to supply samples by a manufacturer of a product subject to REMS under certain circumstances. Senator Patrick Leahy (D-VT) commented:

> The first delay tactic addressed by the CREATES Act involves withholding of drug samples that generic manufacturers need to gain regulatory approval. Federal law requires generic competitors to prove that their low-cost alternative is equally safe and effective as the brand-name drug with which they wish to compete. Unfortunately, some brand-name companies are refusing to provide samples of their product to generic companies for them to make the necessary comparison. This simple delay tactic uses regulatory safeguards as a weapon to block competition.[26]

69. Senator Chuck Grassley (R-IA), in that same hearing, echoed Senator Leahy:

> So I was concerned when we heard of other tactics that appeared to frustrate the intent of the Hatch-Waxman Act – a law enacted to streamline and expedite the approval process for generic drugs. We heard that certain brand drug companies were misusing their [REMS] to withhold access to drug samples for [BE] testing and generic drug development in violation of FDA regulations and the Hatch-Waxman Act…. These strategies basically amount to brand

---

[25] Association for Accessible Medicines, *Increase Competition & Access – Support CREATES Act*, https://accessiblemeds.org/campaign/increase-competition-and-access-rems (last visited Feb. 26, 2019).

[26] Hearing Before the Senate Judiciary Committee Subcommittee on Antitrust, Competition Policy and Consumer Rights on "The CREATES Act: Ending Regulatory Abuse, Protecting Consumers, and Ensuring Drug Price Competition," Statement of Senator Patrick Leahy (June 21, 2016), https://www.judiciary.senate.gov/download/06-21-16-leahy-statement-2.

> drug companies using an FDA regulatory process set up as a safety measure, to instead block generic competition.[27]

70. The bill was reintroduced to the Senate on April 27, 2017 and reported to the Senate Judiciary Committee on June 21, 2018. The bill received sweeping support from Republican Senators Ted Cruz and Mike Lee, as well as Democratic Senators Dianne Feinstein and Sheldon Whitehouse. Both liberal and conservative lobby groups support the Bill. If enacted, the CREATES Act would save the government as much as $3.8 billion over ten (10) years as it would increase generic drug production and lower government Medicare and Medicaid costs.

71. Some estimates on the cost of REMS abuse are as high as $5.2 billion on the federal government, $5.8 billion on private insurers, and $1.8 billion for ordinary American consumers.[28]

72. Noticeably, the Pharmaceutical Researchers and Manufacturers of America, with Executive Chairman, Robert Hugin (former CEO of Celgene between 2010 and 2017, and thereafter its Executive Chairman), opposes the Bill. Reportedly, "drug company executives …pour[ed] into Washington on private jets…to push for blocking the CREATES Act from the budget agreement."[29]

73. Similarly, Representative David McKinley of West Virginia introduced the FAST Generics Act bill on April 6, 2017.[30] The bill would require that brand-name manufacturers "not construe or apply any condition or restriction relating to the sale, resale, or distribution of the

---

[27] Hearing Before the Senate Judiciary Committee Subcommittee on Antitrust, Competition Policy and Consumer Rights on "The CREATES Act: Ending Regulatory Abuse, Protecting Consumers, and Ensuring Drug Price Competition," Prepared Statement of Senator Chuck Grassley, Chairman (June 21, 2016), https://www.judiciary.senate.gov/download/06-21-16-grassley-statement.

[28] Alex Brill, *Unrealized Savings from the Misuse of REMS and Non-REMS Barriers* (Sept. 2018), https://accessiblemeds.org/sites/default/files/2018-9/REMS_WhitePaper_September2018%5B2%5D.pdf.

[29] David Dayen, *Senate Republicans Kept Provision To Fight High Drug Prices Out of Spending Bill, Democrats Say*, THE INTERCEPT (Feb. 8, 2018), https://theintercept.com/2018/02/08/spending-bill-creates-act-drug-prices/.

[30] Fair Access for Safe and Timely Generics Act of 2017, H.R.2051, 115th Congress (1st Session 2017).

covered product, including any condition or restriction adopted, imposed, or enforced as an aspect of a [REMS] strategy, in a way that restricts or has the effect of restricting the supply of such covered product to an eligible product developer for development or testing purposes." The bill was referred to the House Subcommittee on Health on April 7, 2017.

74. In an effort to combat rampant REMS abuse and to facilitate access to samples of REMS-subjected drugs, the FDA began issuing "safety determination" letters to brand companies that confirmed that the FDA would not consider providing samples of the RLD for generic BE testing to be a violation of REMS. In 2014 the FDA stated:

> In the interest of facilitating prospective generic applicants' access to RLD supplies to conduct the testing necessary to support ANDA approval, FDA has, on request, reviewed the [generic's] BE study protocols proposed by prospective ANDA applicants to assess whether they provide safety protections comparable to those in the applicable REMS ETASU. When the Agency has determined that comparable protections existed, FDA has issued letters to the RLD sponsors stating so and indicating that FDA would not consider it to be a violation of the REMS for the RLD sponsor to provide drug product to the prospective ANDA applicant.[31]

75. Despite FDA's efforts to help generic manufacturers by issuing such letters, FDA continues to reiterate that there is no requirement that a generic company seek or obtain such a letter from the FDA: "Requesting or obtaining such a letter from FDA is not a legal requirement."[32]

---

[31] FDA Center for Drug Evaluation and Research, *Draft Guidance: How to Obtain a Letter from FDA Stating that Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable REMS for RLD* (Dec. 2014), *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/how-obtain-letter-fda-stating-bioequivalence-study-protocols-contain-safety-protections-comparable* ("2014 Draft Guidance").

[32] 2014 Draft Guidance.

76. In 2016, a Senate committee concluded that the FDA has "attempted to stymie [brand manufacturers'] obstruction" by providing letters to generic companies indicating that the agency "see[s] no safety risk," but its "actions have been largely ineffective."[33]

77. In 2017, the FDA committed to responding to generic manufacturers' inquiries seeking help accessing samples within sixty (60) days of receipt to mitigate and shorten the delay brand-manufacturers' scheme imposes.

78. On July 27, 2017, the Federal Trade Commission ("FTC") in a Prepared Statement delivered to the United States House of Representatives Subcommittee on Regulatory Reform, Commercial and Antitrust Law warned that "[d]espite clear guidance from both Congress and the FDA that drug firms should not use REMS programs to block or delay generic or biosimilar competition, complaints about abuse of the regulatory process persist…One study estimates that Americans have lost $5.4 billion in annual savings due to delays in accessing drug samples caused by REMS misuse and other non-FDA mandated restricted distribution programs."[34] In that statement, the FTC explicitly referenced Celgene's actions with respect to Thalomid and Revlimid.

79. On May 17, 2018, FDA announced that it would begin to regularly publish a list of brand-name drugs that have been the target of complaints that their NDA-holder (or manufacturer) is denying access to samples of RLDs when generic companies seek to buy them. The initial list confirmed that the FDA sent at least twenty-one (21) safety determination letters to at least six (6)

[33] *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System,* Senate Special Comm. on Aging, 114th Cong. 115 (December 2016), https://www.aging.senate.gov/imo/media/doc/Drug%20Pricing%20Report.pdf.

[34] *Antitrust Concerns and the FDA Approval Process*, Prepared Statement Markus H. Heier, Bureau of Competition, Federal Trade Commission before the Subcommittee on Regulatory Reform, Commercial and Antitrust Law, Judiciary Committee, United States House of Representatives, Washington, D.C. (July 27, 2017), https://www.ftc.gov/public-statements/2017/07/prepared-statement-federal-trade-commission-antitrust-concerns-fda.

brand companies. Its larger list documented fifty-seven (57) different drugs with annual combined sales of $13.0 billion, to which sample access had been denied.

80. Celgene is listed thrice on the list, as FDA received numerous access inquiries for Celgene's Thalomid, Revlimid, and a third drug not subject to this Complaint, Pomalyst (pomalidomide).[35] The FDA received ten (10) inquiries related to Thalomid, thirteen (13) inquiries related to Revlimid, and eight (8) inquiries related to Pomalyst. FDA issued at least four (4) safety letters for Revlimid, including on July 21, 2012, May 19, 2014, February 22, 2017, and August 15, 2017. FDA issued safety letters for Thalomid on December 12, 2007, and January 17, 2008.

81. FDA Commissioner Scott Gottlieb stated:

> Today, we're making public a list of companies that have potentially been blocking access to the samples of their branded products. We hope that this increased transparency will help reduce unnecessary hurdles to generic drug development and approval. We often hear of these tactics when it comes to generic drug developer access to samples when the brand products are subject to limited distribution programs. In some cases, these limitations on distribution may be asserted relating to a Risk Evaluation and Mitigation Strategy ("REMS"), a program that the FDA implements for certain drugs to help ensure that the benefits of these drugs outweigh their risks.[36]

82. Gottlieb, in an earlier speech noting the pervasiveness of REMS abuse commented "My message is this: end the shenanigans." He continued:

> [B]randed companies' use of REMS — which FDA adopts as a way to ensure the safe use of certain drugs — is also sometimes being used as a way to frustrate the ability of generic firms to purchase the doses of branded drug that they need to run their studies. This needs to stop… I

---

[35] FDA, *Reference Listed Drug (RLD) Access Inquiries*, https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm607738.htm (last visited Feb. 26, 2019).

[36] *Statement from FDA Commissioner Scott Gottlieb, M.D., on new agency efforts to shine light on situations where drug makers may be pursuing gaming tactics to delay generic competition* (May 17, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm607930.htm.

> consider these tactics unfair and exploitative practices, and they're in direct conflict with our broader public health goals.[37]

83. Then, in a statement it gave to the Department of Health and Human Services in July 2018, the FTC urged action that "carefully considered regulatory and legislative efforts to address REMS abuse."[38] FTC went on that "[b]y improperly blocking the product developer from obtaining samples, the branded manufacturer can potentially delay or indefinitely block generic or biosimilar competition to its product, thereby reducing the competition that Congress specifically sought to facilitate via the Hatch-Waxman Act…."[39]

84. On October 3, 2018, the FTC delivered a prepared statement before the Senate Subcommittee on Antitrust, Competition Policy and Consumer Rights, noting that brands continue to "misuse REMS restrictions to prevent or delay generic firms from obtaining FDA approval for lower cost drugs…."[40]

85. On December 20, 2019, Congress enacted material portions of the CREATES Act. It establishes a standalone private right of action for qualifying developers of generic drugs to sue branded drug manufacturers, like Celgene, that refuse "to provide sufficient quantities of the covered product to the eligible product developer on commercially reasonable, market-based terms."

---

[37] Scott Gottlieb, M.D., Commissioner of Food and Drugs, Remarks at the Federal Trade Commission: Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics (Nov. 8, 2017), https://www.fda.gov/NewsEvents/Speeches/ucm584195.htm.

[38] *Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*, Statement of the Federal Trade Commission to the U.S. Department of Health and Human Services (July 16, 2018), *available at* www.ftc.gov/system/files/documents/advocacy_documents/statement-federal-trade-commission-department-health-human-services-regarding-hhs-blueprint-lower/v180008_commission_comment_to_hhs_re_blueprint_for_lower_drug_prices_and_costs. pdf.

[39] *Id.*

[40] *Oversight of the Enforcement of the Antitrust Laws,* Prepared Statement of the Federal Trade Commission before the Subcommittee on Antitrust, Competition Policy and Consumers Rights, Judiciary Committee, U.S. Senate (Oct. 3, 2018).

86. The passage of the bipartisan bill confirms the anticompetitive harm inflicted by brand manufacturers, like Celgene, that abuse the REMS process to unlawfully monopolize the market for a drug by excluding generic competition beyond the period in scope afforded by a lawfully obtained patent. CREATES acknowledges the rampant abuse of the REM system by manufacturers like Celgene and seeks to mitigate the harm that such unlawful behavior has and continues to impose on the American market for drugs. As such, CREATES is a confirmation of the central unlawfulness of REMS abuse and an attempt to pragmatically address it.

87. The need to address REMS abuse through CREATES was not a function of any ambiguity in the law, but rather an acknowledgement that a unified chorus of regulatory officials and legislators had failed to deter REMS abuse despite years of denunciations, issuing of nonbinding comments, investigations, and public shaming, which often singled out Celgene's REMS abuse, as detailed above, in connection with the subject drugs in this case.

g. The Citizens Petition

88. Section 505(j) of the FDCA creates a mechanism that allows a person to file a petition with the FDA requesting that the agency take, or refrain from taking, any form of administrative action. This is known as a "citizen petition."

89. A citizen petition allows a citizen to notify the FDA of its genuine concerns about safety, scientific, or legal issues regarding a product at any time before or after it enters the market.

90. Pursuant to FDA regulations, the FDA Commissioner must respond to a citizen petition within 180 days of receipt with a grant in whole or in part, or a denial of the petition. The Commissioner can provide a tentative response with an estimate on a time for a full response.

91. Gary Buehler, R.Ph., former Director of the Office of Generic Drugs ("OGD"), at CDER, noted that of forty-two (42) citizen petitions raising issues about the approvability of generic products, "very few...have presented data or analysis that significantly altered the FDA's

policies." Despite this, it is standard practice for the FDA to withhold ANDA approval until it has completed its research into, and responded to, a citizen petition.

92. Responding to a citizen petition strains the FDA's limited resources. Regardless of how frivolous a petition may be, the FDA must expend considerable resources researching the petition's scientific, medical, legal, and economic issues, delaying ANDA approval, even if a petition is later found to be baseless.

93. Frivolous petitions sponsored by branded drug manufacturers have become an increasingly common tactic to delay generic competition.

94. In many cases, citizen petitions have been filed relating to ANDAs that have been pending for over a year, long after the brand manufacturer received notice of the ANDA filing. In these cases, the petition delays the ANDA approval while the FDA evaluates the citizen petition. In most cases, there is no reason for the brand manufacturer's delay in filing the citizen petition.

95. The FDA has acknowledged manipulation of the citizen petition review process. Former FDA Chief Counsel Sheldon Bradshaw recognized that during his tenure he had "seen several examples of citizen petitions that appear designed not to raise timely concerns with respect to the legality of scientific soundness of approving a drug application but that to try to delay the approval simply by compelling the agency to take the time to consider arguments raised in the petition whatever their merits and regardless of whether or not the petitioner could have made those very arguments months and months before."[41]

h. Patent Prosecution

96. Filing a patent application is an *ex parte* process for which the law imposes a duty of good faith, candor, and disclosure on the filing party.[42] This duty requires the filer, including

[41] 153 Cong. Rec. 127 (Jan. 4, 2007) (statement of FDA Chief Counsel Sheldon Bradshaw in 2005).

[42] *See* 37 C.F.R. § 1.56; Manual of Patent Examining Procedure § 2000.

his or her agents, attorneys, or anyone else involved in the prosecution, to disclose all material information on the patentability of the claims.

97. An applicant's intentional withholding of information known to be material to patentability with the intent to deceive the USPTO constitutes inequitable conduct and renders a patent unenforceable.

98. The existence of prior art is material to patentability.[43] Prior art means that "the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public" or "the claimed invention was described in a patent issued under section 151, or in an application for a patent published or deemed published under section 122(b)...."[44]

VI. CELGENE'S ANTICOMPETITIVE CONDUCT

a. Thalomid and Revlimid

99. In the mid-20th Century, thalidomide was marketed as a sleeping pill and anti-morning sickness pill for pregnant women. Devastatingly, when consumed by pregnant women, thalidomide caused life-threatening fetal deformities and birth defects. Adverse effects also included nerve damage.

100. Thalidomide was thereafter banned worldwide, including in the United States. The U.S. ban was in place until July 16, 1998, when the FDA approved Celgene's December 20, 1996, NDA 20-785 for Thalomid, its branded version of thalidomide. The FDA approved Thalomid only as a treatment for ENL, a form of leprosy.[45] But to mitigate fetal exposure to the drug, the FDA conditioned its Thalomid approval on Celgene's use of the System for Thalidomide Education and

[43] *See* 35 U.S.C. § 102.

[44] 35 U.S.C. § 102(a)(1)-(2).

[45] Thalomid was later approved in 2006 to treat Multiple Myeloma ("MM"), subject again to Celgene's restricted distribution system.

Prescribing Safety ("S.T.E.P.S.") distribution program, in which patients were required to review educational materials, register with the program, and agree to program restrictions. FDA noted, in its Thalomid NDA approval, that "[t]hat current restrictions strike a balance between the need to prevent fetal exposure to the drug and the need to make the drug available without extraordinary burdens on patients and prescribers."

101. After the FDA codified its REMS distribution program, FDA approved Celgene's supplemental application containing a proposed REMS program for Thalomid on August 3, 2010.

102. Celgene filed, prosecuted, and listed in the Orange Book one (1) patent for the Composition of Matter for Thalomid: the '012 Patent, which was first filed with the USPTO in June 2003. Celgene filed, prosecuted and listed a total of fourteen (14) patents in relation to the S.T.E.P.S. and/or REMS programs for controlling Thalomid, and later Revlimid, distribution: the '501 Patent, the '976 Patent, the '432 Patent, the '984 Patent, the '763 Patent, the '188 Patent, the '720 Patent, the '977 Patent, the '784 Patent, the '399 Patent, the '018 Patent, the '566 Patent, the '886 Patent, and the '531 Patent, all of which were filed with the USPTO between August 1998 and August 2012.

103. Revlimid is an immunomodulatory drug that works against cancer cells by affecting the immune system. It is a thalidomide analogue manufactured and marketed by Celgene. Celgene submitted NDA 21-880 to the FDA, which provides for the use of Revlimid to treat patients with transfusion dependent anemia due to low or intermediate-1 risk myelodysplastic syndromes associated with a deletion 5 q cytogenetic abnormality with or without additional cytogenetic abnormalities, on April 7, 2005. The FDA approved Revlimid on December 27, 2005. Celgene was granted exclusivity for Revlimid as it was a new chemical entity ("NCE"); exclusivity expired on December 27, 2010. Competition, absent anticompetitive misconduct, would normally begin immediately after Celgene's exclusivity expired.

104. Revlimid is subject to a REMS distribution program, RevAssist. The primary goal of the RevAssist program, approved by the FDA, is to prevent fetal exposure to Revlimid. FDA noted in its December 27, 2005, letter to Celgene that RevAssist is "an important part of the post-marketing risk management for Revlimid®."

105. In addition to the patents listed in the Orange Book, Celgene was issued numerous additional patents related to thalidomide and its analogs. According to 21 U.S.C. § 355(b)(1), NDA applicants shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. Despite not listing these patents, indicating a belief that an infringement claim could not reasonably be asserted, Celgene made frivolous infringement claims for these patents in response to ANDAs for lenalidomide, as discussed below.[46]

106. Celgene also filed, prosecuted, and listed in the FDA Orange Book three (3) patents for the Composition of Matter for Revlimid; the '517 Patent, which was first filed with the USPTO in July 1996, and the two polymorph patents, the '800 Patent and the '217 Patent, first filed with the USPTO in September 2004 and December 2008, respectively (the "Polymorph patents"). Celgene filed, prosecuted, and listed several patents in relation to the RevAssist program for controlling Revlimid distribution; the '501 Patent, the '976 Patent, the '432 Patent, the '763 Patent, the '188 Patent, the '720 Patent, the '977 Patent, the '784 Patent, the '886 Patent, and the '531 Patent, which were filed with the USPTO between August 1998 and August 2012. Celgene filed, prosecuted, and listed a total of ten (10) patents related to the dosage and methods of treatment for

[46] Celgene also filed and prosecuted several additional patents that it did not list in the Orange Book. They are Patent Nos. 6555554 (the "'554 Patent"), 7119106 (the "'106 Patent"), 6281230 (the "'230 Patent"), 6767326 (the "'326 Patent"), 7977357 (the "'357 Patent"), 8193219 (the "'219 Patent") and 8431598 (the "'598 Patent").

Revlimid; the ’740 Patent, the ’569 Patent, the ’363 Patent, the ’929 Patent, the ’717 Patent, the ’095 Patent, the ’120 Patent, the ’498 Patent, the ’621 Patent, and the ’622 Patent, filed with the USPTO between April 2003 and September 2014. Another patent, the ’745 Patent, was filed in 2006, and was part of a pattern by Celgene of prosecuting invalid and unenforceable patents to erect an impenetrable “patent fortress” around its Thalomid and Revlimid monopolies.

107. Witness below a chart of Celgene’s patent protection web:

Patent	Number	Date Filed	Date Issued	Expiration Date	Description	Drugs
Composition of Matter						
’517 Patent	5,635,517	24-Jul-96	3-Jun-97	4-Oct-19	Method of reducing TNF.alpha. levels with amino substituted 2-(2,6-dioxopiperidin-3-yl)-1-oxo-and 1,3-dioxoisoindolines	Revlimid
’012 Patent	7,230,012	30-Jun-03	12-Jun-07	9-Dec-23	Pharmaceutical compositions and dosage forms of thalidomide	Thalomid
Polymorph						
’800 Patent	7,465,800	3-Sep-04	16-Dec-08	27-Apr-27	Polymorphic forms of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione	Revlimid
’217 Patent	7,855,217	15-Dec-08	21-Dec-10	24-Nov-24	Polymorphic forms of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione	Revlimid

REMS						
’501 Patent	6,045,501	28-Aug-98	4-Apr-00	28-Aug-18	Methods for delivering a drug to a patient while preventing the exposure of a fetus or other contraindicated individual to the drug	Thalomid Revlimid (Pomalyst)
’976 Patent	6,561,976	26-Sep-01	13-May-03	28-Aug-18	Methods for delivering a drug to a patient while preventing the exposure of a fetus or other contraindicated individual to the drug	Thalomid Revlimid (Pomalyst)
’432 Patent	6,908,432	22-Jan-04	21-Jun-05	28-Aug-18	Methods for delivering a drug to a patient while preventing the exposure of a fetus or other contraindicated individual to the drug	Thalomid Revlimid (Pomalyst)
’984 Patent	7,874,984	12-Apr-05	25-Jan-11	28-Aug-18	Methods for delivering a drug to a patient while preventing the exposure of a fetus or other contraindicated individual to the drug	Thalomid
’763 Patent	8,204,763	13-Dec-	19-Jun-12	28-Aug-	Methods for delivering a drug to a patient while preventing the	Thalomid Revlimid

		10		18	exposure of a fetus or other contraindicated individual to the drug	(Pomalyst)

’188 Patent	8,589,188	17-May-12	19-Nov-13	28-Aug-18	Methods for delivering a drug to a patient while preventing the exposure of a fetus or other contraindicated individual to the drug	Thalomid Revlimid (Pomalyst)
’720 Patent	6,315,720	23-Oct-00	13-Nov-01	23-Oct-20	Methods for delivering a drug to a patient while avoiding the occurrence of an adverse side effect known or suspected of being caused by the drug	Thalomid Revlimid (Pomalyst)
’977 Patent	6,561,977	27-Sep-01	13-May-03	23-Oct-20	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid Revlimid (Pomalyst)
’784 Patent	6,755,784	7-Mar-03	29-Jun-04	23-Oct-20	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid Revlimid (Pomalyst)
’399 Patent	6,869,399	22-Jan-	22-Mar-05	23-Oct-20	Methods for delivering a drug to a patient while restricting access to	Thalomid

		04			the drug by patients for whom the drug may be contraindicated	
’018 Patent	7,141,018	3-Jan-05	28-Nov-06	23-Oct-20	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid
’566 Patent	7,959,566	19-May-06	14-Jun-11	23-Oct-20	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid
’886 Patent	8,315,886	13-Dec-10	20-Nov-12	23-Oct-20	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be Contraindicated	Thalomid Revlimid (Pomalyst)
’531 Patent	8,626,531	22-Aug-12	7-Jan-14	23-Oct-20	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid Revlimid (Pomalyst)
Dosing						
’740 Patent	7,189,740	11-Apr-03	13-Mar-07	11-Apr-23	Methods of using 3-(4-amino-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione for the treatment and management of	Revlimid

					myelodysplastic syndromes	
’569 Patent	7,968,569	15-May-03	28-Jun-11	7-Oct-23	Methods for treatment of multiple myeloma using 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione	Revlimid
’363 Patent	7,468,363	8-Apr-05	23-Dec-08	7-Oct-23	Methods for treatment of cancers using 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione	Revlimid
’929 Patent	8,741,929	19-Nov-09	3-Jun-14	8-Mar-28	Methods using 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione for treatment of mantle cell lymphomas	Revlimid
’717 Patent	8,404,717	24-Mar-11	26-Mar-13	11-Apr-23	Methods of treating myelodysplastic syndromes using Lenalidomide	Revlimid
’095 Patent	8,648,095	5-Jun-12	11-Feb-14	15-May-23	Methods for treating multiple myeloma using 3-(4-amino-1-oxo-1,3-dihydroisoindol-2-yl)-piperidine-2,6-dione in combination with proteasome inhibitor	Revlimid
’120 Patent	9,056,120	13-Mar-13	16-Jun-15	11-Apr-23	Methods of treating myelodysplastic syndromes with a combination therapy using lenalidomide and azacitidine	Revlimid
					Methods for treating	

’498 Patent	8,530,498	8-Apr-13	10-Sep-13	15-May-23	multiple myeloma with 3-(4-amino-1-oxo-1,3-dihydroisoindol-2-yl) piperidine-2,6-dione	Revlimid
’621 Patent	9,101,621	17-Apr-14	11-Aug-15	15-May-23	Methods for treating multiple myeloma with 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione after stem cell transplantation	Revlimid
’622 Patent	9,101,622	10-Sep-14	11-Aug-15	15-May-23	Methods for treating newly diagnosed multiple myeloma 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione in combination with dexamethasone	Revlimid
’745 Patent	7,435,745	26-Apr-06	14-Oct-08	31-Jul-19 (Estimate)	Methods and compositions for inhibition of angiogenesis	Thalomid (Not listed in Orange Book)

b. Celgene Abused Its REMS Program as a Pretextual Justification for Refusing to Sell Samples and Illegally Monopolized the Market

108. Both Thalomid and Revlimid are subject to REMS distribution programs that require healthcare providers and pharmacies to be certified in the S.T.E.P.S. or RevAssist programs, respectively, and patients must be enrolled in S.T.E.P.S. or RevAssist. Prescribers and pharmacists must complete registration forms. Females of childbearing potential are required to take a pregnancy test twenty-four (24) hours prior to starting a course of Thalomid or Revlimid and at least every four (4) weeks during treatment. All prescribers are required to provide contraception and emergency

contraception counseling with each new prescription. For every new patient, prescribers must submit to Celgene a signed Patient-Physician Agreement Form that identifies the patient's risk category. The prescriber then receives a letter confirming the patients' enrollment and the patient and prescriber receive an authorization number which is to be written on the prescription. The pharmacy must verify that each prescription has an authorization number that is valid for seven (7) days. The pharmacy must then call Celgene, obtain a confirmation number, and write this number on the prescription. The prescription is then filled within twenty-four (24) hours. No more than a twenty-eight (28) day supply may be dispensed at one time.

c. Celgene Maintained Monopoly Power Through the Use of Exclusionary Conduct.

109. RevAssist operates through specialty pharmacies. The S.T.E.P.S. program initially operated in all pharmacies. Only in 2006 did S.T.E.P.S. come to exclusively operate through specialty pharmacies. Alexis Tosti, Celgene's Market Research Analyst, noted that moving to a specialty pharmacy would "be a hurdle for generic companies," and that "[r]estricted distribution is more likely to keep thalidomide out of the hands of generic companies who need product to test against the generic being developed," in internal company emails in 2006.[47]

110. A central part of Celgene's monopolistic anticompetitive scheme to unlawfully monopolize the markets for the subject drugs was to abuse REMS and prevent generic manufacturers from obtaining the necessary samples of Thalomid and Revlimid to perform the BE testing needed to file an ANDA.

111. Celgene abused its REMS program as a pretextual justification for withholding Thalomid and Revlimid samples from generic competitors. Among the manufacturers that Celgene refused to supply are Mylan Pharmaceuticals Inc. ("Mylan") between 2004 and the present,

[47] Exhibit to MSJ Opp., Dkt. No. 285-20 at PageID 17672.

Lannett Company ("Lannett") in 2006, Exela Pharmsci, Inc. ("Exela") in 2006, Dr. Reddy's Laboratories ("Dr. Reddy's") in 2008 and 2009, Watson Laboratories, Inc ("Watson") in 2009, Teva Pharmaceuticals USA ("Teva") in 2009, and Sandoz Inc. ("Sandoz") in 2012. Celgene also entered into an exclusive supply agreement with a French thalidomide supplier to prevent Barr Laboratories ("Barr") from obtaining that company's thalidomide active pharmaceutical ingredient ("API").

112. Celgene's improper use of the REMS program as a shield to refuse to provide samples is contrary to the FDAAA. FDAAA subsection f (8) states that "no holder of [a REMS-covered drug] shall use any element to assure safe use…to block or delay approval of… an [ANDA application]."[48]

i. Celgene's REMS Program is a Post-Marketing Distribution System with No Legal or Practical Relation to the Sales of Samples to Competitors.

113. Celgene's REMS distribution programs are post-marketing, commercial distribution programs. Celgene's REMS protocols do not discuss drug manufacturers conducting business with one another in the pre-marketing, drug development phase. Nor do Celgene's REMS protocols discuss or prevent distribution of samples to drug manufacturers.

114. Generic manufacturers' safety protocols are not required to be FDA-approved for that manufacturer to purchase samples of a REMS-subject drug. Robert West, former Deputy Director of OGD, commented that "a generic manufacturer is not required to submit its protocols to the FDA before commencing bioequivalence studies."[49]

115. Clinical and pre-approval studies are not governed by REMS. In an August 2012 meeting with Celgene, the FDA stated, "Celgene's REMS relates to a marketed situation and not

[48] 21 U.S.C. § 355-1(f)(8).

[49] Exhibit to MSJ Opp., Dkt. No. 285-15 at PageID 17061.

a clinical trial where there is more control regarding administration of the product and the amount given is monitored and very limited."

116. A sample supply of a brand-name drug, including the API, is required to manufacture a generic equivalent. The API is used to conduct the required biostudies and validation testing before the generic manufacturer submits its ANDA.

117. Due to Celgene's REMS program, generic manufacturers are unable to purchase Thalomid and Revlimid samples in the United States through normal wholesale distribution channels. They are therefore forced to seek to purchase the drugs directly from Celgene, with the FDA's endorsement.

ii. Celgene Refused to Sell Samples

1. Celgene Refused to Sell Samples to Mylan

118. Celgene refuses to sell Thalomid and Revlimid samples to Mylan, the second largest generic pharmaceutical manufacturer in the world.

119. Mylan began developing a generic thalidomide product on September 26, 2003. On October 27, 2003, Mylan requested OGD provide guidance on prospective BE studies. OGD provided the requested guidance within the following year.

120. On December 22, Mylan requested thalidomide API from API suppliers GYMA Laboratories of America, Inc. ("GYMA") and Antibioticos to manufacture its formulation of thalidomide. By March 11, 2004, Mylan received thalidomide API from Antibioticos.

121. In September 2004, after Mylan was unable to gain access to Thalomid samples, the FDA suggested Mylan contact Celgene to request samples. On October 5, 2004, Mylan wrote Celgene a letter through its attorneys requesting to purchase 2,500 Thalomid capsules to conduct BE studies. Celgene failed to respond. Mylan repeated its request on May 3, 2005. At the time, Mylan had already completed safety training sessions for the handling and testing of thalidomide.

122. In a letter dated June 21, 2005, Celgene explained that pursuant to its S.T.E.P.S. program, Thalomid was not available through normal wholesale channels, and that it was against Celgene's policy to deal with third parties in the sale of Thalomid. Notwithstanding the above, Celgene did not have a single internal discussion finding it would be a violation of S.T.E.P.S. to provide Mylan with Thalomid without FDA approval.

123. In unsealed internal emails from July 6, 2005, Celgene noted that "Mylan has had difficulty obtaining enough of Celgene's reference product to perform the BE studies, so its ANDA submission is expected to be delayed until late in the third quarter of 2005."[50]

124. On September 2, 2005, Mylan directly contacted Celgene and requested to purchase 3,360 Thalomid capsules to conduct BE testing.[51] Mylan explained that the "FDA recommended that we contact you directly to request a sample" of Thalomid for BE testing, and that "obtaining samples through other traditional channels is nearly impossible."[52]

125. On October 20, 2005, Celgene replied, claiming that it needed additional time to consider the request and "to avoid fetal exposure."[53]

126. On November 15, 2005, Mylan used an intermediary to again request that Celgene sell it Thalomid samples for BE testing.

127. By December 2005, Mylan completed its scale-up of its experimental thalidomide batch. Mylan had, by that time, captured two-years' worth of stability data. The only remaining step to submitting its ANDA was to conduct BE studies against the RLD.

---

[50] Exhibit to MSJ Opp., Dkt. No. 286-2 at PageID 18485.

[51] Exhibit to Brief in Support of Motion for Summary Judgment, *Mylan Pharmaceuticals, Inc. v. Celgene Corp.*, No. 2:14-cv-02094-ES-MAH (D.N.J. Mar. 20, 2018) ("MSJ Moving Papers"), Dkt. No. 283-4 at PageID 15196.

[52] *Id.*

[53] Exhibit to MSJ Opp., Dkt. No. 286-2 at PageID 18488.

128. On December 19, 2005, Celgene stated that it would need the FDA's approval to allow Mylan to purchase samples outside of the S.T.E.P.S. program: "[W]e recommend that you contact the FDA's [Division of Special Pathogen and Transplant Products] to discuss the importance of the S.T.E.P.S. program to them."[54] Celgene claimed that if the FDA then "contacts us in writing and recommends that we violate our S.T.E.P.S. program by providing you with the quantity of THALOMID you request, we will further evaluate your request at that time."[55]

129. This is contradicted by an internal report created in 2003 at Celgene's request, Celgene admitted Mylan's patient monitoring system—already in place for another drug it was studying—was robust, comprehensive, and equivalent to the S.T.E.P.S. program.

130. Detailing the manufacturer's procedures, Celgene's report stated that Mylan's safety protocols "currently have very sophisticated patient monitoring systems for their respective clozapine products."[56]

131. Furthermore, the report stated "it can be observed that the clozapine requirements are as comprehensive as the S.T.E.P.S. program. Thus, Ivax and Mylan already have experienced [sic] with sophisticated monitoring systems."[57]

132. Next, Mylan requested FDA assistance to obtain the necessary Thalomid samples required for bioequivalence testing on January 11, 2006. In its letter, Mylan proposed protocols to ensure avoidance of fetal exposure.

133. By emails dated March 3, 2006, Mylan estimated a Thalidomide launch for May 2010.

---

[54] Exhibit to MSJ Moving Papers, Dkt. No. 283-5 at PageID 15205.

[55] *Id.*

[56] Exhibit to MSJ Opp., Dkt No. 286-1 at PageID 18304.

[57] *Id.*

134. On February 12, 2007, the FDA replied, requesting an investigational new drug application ("IND") or study protocol so that it could "ensure that all appropriate safeguards for a clinical investigation with thalidomide are in place," as a substitute for the S.T.E.P.S. program.[58]

135. The FDA's response continued:

> It is the FDA's view that certain restrictions are needed to ensure safe use of the drug; however, it is not the agency's intention to permit the restrictions of the S.T.E.P.S. program to prevent manufacturers of generic drugs from obtaining Thalomid for use in the bioequivalence testing necessary to obtain approval of an abbreviated new drug application for a thalidomide product. The agency believes that such bioequivalence studies can be conducted safely under either an IND or in circumstances that provide alternative assurance of patient safety. To ensure that the intention of Congress in enacting the generic drug approval provisions in section 505(j) is not frustrated by the terms of the S.T.E.P.S. program, FDA has notified Celgene that the agency intends to exercise its enforcement discretion to permit Celgene to provide to another drug manufacturer (or its agent) 500 units of Thalomid (including 200 units for the purpose of conducting bioequivalence (including dissolution) testing and 300 units for a limited number of retained samples) when Celgene has received confirmation in writing from the sponsor, its agent, or FDA that the sponsor of the study either has an IND in effect for the study or has otherwise provided the agency with sufficient assurance that the bioequivalence study will be conducted in such a manner as to ensure the safety of the subjects.[59]

136. On May 1, 2007, Mylan produced to the FDA its proposed thalidomide safety protocols, which the FDA reviewed, found "acceptable," and so notified Mylan on September 11, 2007.

137. On November 16, 2007, Mylan notified Celgene of the FDA's approval, which directly addressed Celgene's pretextual justification for not providing samples. Celgene's senior executives and officers all admit that the FDA is the ultimate authority on setting safety standards.

[58] Exhibit to MSJ Moving Papers, Dkt. No. 283-6 at PageID 15255.
[59] *Id.*

Yet Celgene continued to deny Mylan's and others requests for drug samples for BE testing, using pretextual and obviously flawed safety concerns as its chief justification.[60]

138. Undeterred, Mylan continued to make requests over the next three (3) years, including on December 4, 2007. Celgene continued to refuse to produce Thalomid samples, using delay tactics including requiring Mylan to produce burdensome, irrelevant, and duplicative information. Meanwhile, Celgene internally admitted that another prospective ANDA filer's request was "deficient in a way that the Mylan request is not."

139. On January 8, 2008, Celgene wrote Mylan requesting more information. Mylan responded on February 25, 2008, writing that it was prepared to provide all requested information and enclosed a confidentiality agreement. Celgene and Mylan negotiated the confidentiality agreement until June 24, 2008, when Celgene sent Mylan the executed agreement. Mylan sent Celgene another letter providing even more information and provided Celgene with proof of liability insurance covering any instances of injury relating to drug's misuse, and further provided an indemnity contract.

140. This contract, which was extensively negotiated, agreed to hold Celgene harmless in the event of any injury or misuse.

141. Celgene wrote Mylan on August 1, 2008, that it was reviewing Mylan's documentation. Celgene's then-Regulatory Counsel testified that as of March 4, 2011, no "business people" at Celgene reviewed any of Mylan's documentation. Confoundingly, Celgene served an interrogatory response in an FTC investigation stating that two former CEOs, Sol Barer and Robert Hugin, "made the decisions on behalf of Celgene regarding Celgene's responses to pharmaceutical companies requesting to purchase Thalomid® and Revlimid® with legal advice

[60] On April 21, 2000, the FDA sent Celgene a "Warning Letter" stating that "Celgene ha[d] engaged in promotional activities that state or suggest that Thalomid is safe and effective for use in treating multiple myeloma." With no generics on the horizon, Celgene was willing to play fast and loose with the safe distribution of Thalomid so long as it ensured increased utilization and increased profits.

from Celgene's Deputy General Counsel and then-Regulatory and Compliance Counsel." The referenced in-house counsel later testified in a separate litigation that they did not have any input into the requests, could not recall reviewing a single response to one of the information requests submitted to Celgene, or sitting in a meeting in which a response to a prospective ANDA filer's request was discussed. Upon information and belief, Celgene lied to the FTC in its interrogatory response.

142. Celgene wrote Mylan in a June 24, 2009, letter that there were "outstanding issues" with the information Mylan provided and requested nine (9) additional categories of information. An internal Celgene email dated May 22, 2009, contained a project titled "Thalidomide Multiple Myeloma." The summary of the project stated "A generic thalidomide application was successfully delayed until at least June '09 in the USA. Celgene may further extend its exclusivity in the USA by using bioequivalence as a generic defense strategy…." Celgene's own emails show that it was never truly concerned with the safe distribution of its drugs, but rather used safety as a pretextual justification to prevent generic competition.

143. Celgene's refusal to sell Mylan samples, despite the existence of liability insurance and an indemnity contract, is further evidence Celgene was unwilling to negotiate in good faith with generic manufactures to provide the requested drugs. This Court previously found, based on these facts, that one could reasonably infer "that Celgene had no objectively legitimate business justification for not selling Mylan samples of Thalomid® or Revlimid® samples after FDA approval of Mylan's study protocols."[61]

144. Mylan estimates that had Celgene provided it with Thalomid samples in 2006, it would have filed a Paragraph IV Certification, Celgene would have initiated a patent infringement

[61] *Mylan Pharma Inc. v. Celgene Corp.*, No. 14-cv-2094, ECF No. 287, 35 (D.N.J. Oct. 3, 2018).

litigation and Mylan could have ultimately entered the thalidomide market in the third quarter of 2010.

145. By June 2007 Mylan began to develop its generic Revlimid. In internal emails from September 2007, Mylan planned to file its ANDA on December 27, 2009, was actively sourcing raw materials, had opinions on the blocking compound patents and planned to design around the formulation patent.

146. In early 2009, Mylan endeavored to purchase lenalidomide supplies to manufacture a generic version of Revlimid. Celgene engaged in more delay tactics, causing Mylan to cease development efforts at various points while it attempted to procure Revlimid samples. Mylan manufactured its final lenalidomide formulation in June 2015.

147. In June 2010, in response to FTC interrogatories, Celgene explained to the FTC that "Celgene has decided not to sell REVLIMID® at the present time to manufacturers."[62]

148. Over two years later, through its counsel, Celgene wrote to the FTC that it was willing to "continue selling Thalomid and begin to sell Revlimid to drug companies, branded or generic, in quantities authorized by the FDA sufficient to conduct bio equivalence studies for the purpose of preparing an Abbreviated New Drug Application [ANDA] with the FDA."[63] Celgene, at no point prior to this email, ever sold Thalomid to generic drug companies to support BE studies for the purpose of preparing ANDAs. Celgene's letter continued: "[Celgene would] seek to set appropriate conditions with the FDA for the sale of Revlimid similar to those it has set for the sale of Thalomid…."

149. On August 14, 2012, Celgene wrote to the FDA claiming that the FDCA does not require an RLD sponsor to provide drug product to a proposed ANDA filer, and that FDA does

[62] Exhibit to MSJ Opp., Dkt. No. 286-4 at PageID 18669.

[63] *Id*. at Page ID 18671.

not have authority to mandate any such requirement. Celgene even threatened that "any sale of Revlimid to a generic manufacturer will not be effectuated unless and until the FTC and the State of Connecticut Attorney General agree to close their investigation."[64]

150. On May 1, 2013, Mylan requested to purchase Revlimid samples from Celgene at market value. On May 14, 2013, Celgene wrote to Mylan that it would sell Revlimid to Mylan upon Celgene's review of Mylan's request and supporting documentation.

151. While not required to do so, Mylan sought FDA approval of its proposed safety protocols to avail itself of any assistance the FDA might be able to offer in procuring Revlimid samples. The FDA approved Mylan's protocols on July 29, 2013.

152. On March 11, 2014, Mylan wrote to Celgene explaining that it received all necessary approvals from the FDA. Celgene continued to refuse to provide samples, even, once again, after being informed of FDA approval for the proposed BE testing and safety protocols.

153. On March 20, 2014, Celgene again wrote to Mylan refusing to sell Mylan Revlimid samples. Exasperated with Celgene's tactics, Mylan brought a suit on April 3, 2014 against Celgene under federal and state antitrust laws for its anticompetitive tactics to maintain monopoly power in the market for Thalomid and Revlimid.

154. Mylan alleges that Celgene cited safety concerns as a pretext for its continued refusal to provide samples of Thalomid and Revlimid, and that Celgene used a "playbook of obstruct[ion]" and "gam[ed] the regulatory system."[65]

155. On May 19, 2014, the FDA notified Celgene that it accepted Mylan's submitted lenalidomide safety protocols and reiterated the FDCA's prohibition of using REMS to prevent ANDA filers from accessing drug samples.

---

[64] Exhibit to MSJ Opp., Dkt. No. 285-15 at PageID 17053.
[65] *Mylan Pharma Inc. v. Celgene Corp.*, No. 14-cv-2094 (D.N.J. Apr. 3, 2014), Dkt. No. 1 ¶8.

156. The FTC filed an amicus brief in support of Mylan's suit against Celgene. The FTC noted that the FDAAA was intended to prevent brand-name manufacturers from using REMS programs to impede generic competition, as Celgene was doing with Thalomid and Revlimid.

157. Further, in August 2012, the FTC sent counsel for Celgene an email detailing "a number of questions" raised by "the Bureau of Competition and the staff of the Connecticut Attorney's General office."[66]

158. These concerns included questions surrounding why Celgene had yet to provide samples of Thalomid to those requesting it, despite receiving explicit authorization from the FDA to do so.

159. The letter also questioned what else Celgene would need to receive in order to authorize the sale of Revlimid to generic manufacturers: "in the interest of advancing our discussions and trying to reach a prompt resolution with you, we propose the FTC and Celgene meet together with the FDA . . . to discuss what Celgene thinks it needs from the FDA in order to be able to make prompt sales to generic firms."[67]

160. The FTC's Bureau of Competition ("BOC") followed up on this letter with another round of correspondence in February 2013.

161. In an e-mail to Celgene's counsel, Richard A. Feinstein, the director of the BOC stated "that there is a lot of concern here-at both the Bureau and Commission levels- about the time it has taken for your client to [redacted] of Revlimid capsules for bio-equivalence testing…the Commission's patience is wearing thin. We have reached a point where the staff may be instructed in the very near future to commence litigation."

162. Counsel for Celgene quickly forwarded this email Celgene executives.

[66] Exhibit to MSJ Opp., Dkt. No. 285-16 at PageIDs 17354-55.
[67] *Id.*

163. Most of Mylan's claims survived Celgene's motion to dismiss. Celgene subsequently filed its motion for summary judgment. On October 3, 2018, Celgene's motion was granted in part and denied in part.[68]

164. One of Mylan's expert witnesses in that litigation, Paul J. Jarosz, Ph.D., stated that Mylan's development process was typical for the pharmaceutical industry and that "[h]ad Mylan been able to purchase Thalomid so that it could dose its bioequivalence studies and receive an approval for its generic drug application, Celgene's '012 Patent and claim 2 of its '327 Patent would have not have prevented Mylan from launching its generic thalidomide product as the claims are invalid due to prior art and/or Mylan's formulation does not infringe them."[69]

165. Regarding generic Revlimid, Dr. Jarosz stated that "based on the simple nature of Revlimid and Mylan's previous experience developing thalidomide, it appears that Mylan could have developed and filed an application for generic lenalidomide product by December 27, 2009."[70]

166. Dr. Jarosz's report confirms that the inability of generic drug manufacturers to bring versions of Thalomid and Revlimid to market were not due to internal issues or manufacturing defects. Instead, his report reinforces the fact that the only barrier to entry in the market was Celgene's conduct.

167. Mylan never received Revlimid samples. Celgene's continued refusal to provide samples of Thalomid and/or Revlimid only further elucidates that Celgene's refusal based on safety concerns was and continues to be a conveniently fabricated excuse to frustrate competition.

---

[68] *Mylan Pharma Inc. v. Celgene Corp.*, No. 14-cv-2094, Dkt. No. 287 (D.N.J Oct. 3, 2018).

[69] Exhibit to MSJ Opp., Dkt. No. 285-21 at PageID 17757.

[70] *Id.*

168. On August 1, 2019, Celgene announced that it reached a settlement with Mylan. On August 8, 2019, the District Court entered a consent judgment dismissing all claims with prejudice. Celgene disclosed that it agreed to pay $62 million to Mylan to resolve all claims.

a. Mylan Strong Safety Protocols Confirm and Illustrate The Pretextual And Unlawful Nature Of Celgene's Refusal To Sell Samples To Would Be Competitors

169. In September 2011, Sofgen Pharmaceuticals ("Sofgen") contacted Mylan regarding the potential purchase of Amnesteem for BE testing.

170. Like lenalidomide and thalidomide, Amnesteem is a known human teratogen, and was under FDA restriction for sale and delivery.

171. Sofgen knew of these restrictions and reached out to the FDA prior to contacting Mylan to receive an assurance its iPLEDGE safety restrictions were acceptable and allowed it to receive a drug known to be a human teratogen.

172. The FDA sent Sofgen a letter in response, confirming Sofgen's iPLEDGE procedures were adequate under current FDA guidelines.

173. Mylan and Sofgen entered into successful negotiations surrounding Sofgen's purchase of Amnesteem samples from Mylan. This included the drafting of an indemnity agreement, discussions on the purchase price, and the method for payment and delivery. The sale was completed, and samples were delivered to Sofgen in Spring 2011.

174. Unlike Celgene, Sofgen and Mylan's discussions surrounding the purchase of Amnesteem show that receiving an approval letter from the FDA removes any perceived roadblocks to sharing a drug sample for BE testing.

175. Mylan's contract with Sofgen shows the process for obtaining generic drug samples can be completed in a short timeframe, and without the unnecessary and burdensome documentation Celgene requested from numerous generic manufacturers.

176. Further, another expert hired by Mylan in its lawsuit against Celgene, Jeff Fetterman, opined that Mylan's experience with the REMS process was robust and extensive, and it would have no issues implementing one for generic thalidomide and lenalidomide.[71]

177. As Mr. Fetterman stated in his report, "Mylan has extensive experience developing, implementing, and managing risk management programs, including several REMS programs with the same or similar restrictions and requirements as the S.T.E.P.S. and RevAssist programs."[72]

178. Mr. Fetterman continued and stated "[i]f Celgene had provided brand samples to Mylan and cooperated in developing a shared REMS program for thalidomide, the SS REMS development and FDA approval likely would have taken 18 to 24 months. Furthermore, this estimate may be conservative, as an alternative parallel agreement to sign onto the S.T.E.P.S. program would have taken even less time, possible in as few as 12 months. All of this work could have begun in advance of Mylan's ANDA approval…."[73]

179. Mr. Fetterman's report details further how Celgene's refusal to provide drug samples on the basis of noncompliance with REMS procedures was a misdirection and stall tactic not based in truth or fact.

2. Celgene Refused to Sell Samples to Exela.

180. On May 31, 2006, Exela contacted Celgene and informed it of Exela's intention to file an ANDA for Thalomid. Exela stated it was having difficulty obtaining samples of this drug from other channels, much like the other generic manufactures who had contacted Celgene. Exela requested a proposal for purchase within 10 days.

[71] Exhibit to MSJ Opp., Dkt. No. 286-2 at PageIDs 18325-70.

[72] *Id.* at PageID 18327.

[73] *Id.* at PageIDs 18355-56.

181. On June 27, 2006, Exela sent a follow up letter to Celgene again requesting to purchase Thalomid samples. In its letter, Exela noted the 10-day window for a purchase proposal had lapsed despite being received the day after it was sent.

182. On September 11, 2007, OGD wrote to Exela that its "proposed bioequivalence study protocol comparing Thalidomide Capsules, 200 mg to [Thalomid] is acceptable…."

183. On December 11, 2007, OGD Director Gary J. Buehler sent a letter to Celgene's internal regulatory counsel, Kerry Rothschild stating that "FDA has reviewed the bioequivalence protocol submitted…on behalf of Exela and has received sufficient assurance that the bioequivalence study will be conducted in such a manner as to ensure the safety of the subjects and has determined that Celgene may provide Exela with 500 units of Thalomid as indicated in FDA's letter to you dated February 8, 2007 for the purposes of conducting an in vivo bioequivalence study and in vitro dissolution testing."

184. Over a year later, on January 8, 2008, counsel for Celgene contacted counsel for Exela regarding the Thalomid purchase request.

185. In a response almost identical to ones given to other generic manufactures, Celgene stated it did not believe it was obligated to turn over any samples. However, it continued that if Exela were to comply with a list of 10 demands for information, including, for example, proof of liability insurance and a history of product loss due to improper handling or tracking, Celgene would then "reconsider" its denial. Upon information and belief, Celgene never provided Exela with the requested samples of Thalomid.

3. Celgene Refused to Sell Samples to Lannett.

186. On September 6, 2006, Lannett wrote a letter to the FDA requesting BE recommendations regarding thalidomide capsules.

187. The FDA's OGD responded to Lannett's letter on February 12, 2007. The OGD stated that "it is not the agency's intention to permit the restrictions of the S.T.E.P.S. program to prevent manufacturers of generic drugs from obtaining Thalomid for use in the bioequivalence testing necessary to obtain approval of an abbreviated new drug application for a thalidomide product."

188. The OGD commented that, to ensure Congress' intentions in enacting the Generic Drug Approval Provisions in Section 505(i) are carried out, the "FDA has notified Celgene that the agency intends to exercise its enforcement discretion to permit Celgene to provide to another drug manufacturer (or its agent) 500 units of Thalomid… for the purpose of conducting bioequivalence testing."

189. The FDA did so notify Celgene, on February 8, 2007, that "a study protocol would be reviewed by FDA to ensure that all appropriate safeguards for a clinical investigation with thalidomide are in place" if a proposed generic manufacturer wished to conduct BE studies. FDA explained that it would "exercise its enforcement discretion to permit Celgene to provide to another drug manufacturer (or its agent) 500 units of Thalomid for the purpose of conducting [BE] testing, when Celgene has received confirmation in writing from the sponsor, its agent, or FDA that the sponsor of the study either has an IND in effect for the study or has otherwise provided the agency with sufficient assurance that the [BE] study will be conducted in such a manner as to ensure the safety of the subjects."

190. FDA's letter also requested Celgene submit a supplement to its own Thalomid NDA to the same effect. Celgene failed to submit this supplement, evidencing its own disregard for safety, non-monetarily incentivized circumstances.

191. Nevertheless, Celgene's then-regulatory counsel Kerry Rothschild testified that the FDA's February 8, 2007 letter did not fully assuage Celgene's worry that a fetal exposure and birth of a baby with thalidomide-recognizable defects would have consequences to the value of

Celgene's business.[74] Celgene Chief Executive Officer, Mark Alles, testified in 2016 that of the small number of fetal exposures to Thalomid between its development and 2016, the exposures "had minimal impact on the business as far as I know…."[75]

Celgene's CEO responded to the email in a similarly unalarmed manner.

192. In a July 26, 2007, letter to Celgene, Arthur P. Bedrosian, President and CEO of Lannett, wrote:

> In order to complete our bio-study, the FDA has instructed us to purchase 250 Thalomid 200 MG Capsules from you. We kindly request information as to how to best carry out this transaction. We will be happy to supply a purchase order once you provide us with the total product cost. Submitted with this document, you will find the appropriate licenses necessary for us to purchase the product from you. We kindly ask that you inform us of any additional information you will need to complete this transaction.

193. Upon information and belief, in September 2007, Lannett faxed to Celgene's Darnell Ragland, Manager, Customer Care of Celgene, a requested copy of the February 12, 2007, FDA letter, which authorized Lannett to acquire Thalomid supplies from Celgene.

194. Celgene continued to refuse Lannett's request. Celgene even went as far as actively screening any communication from Lannett directed towards Celgene regarding requests for samples of Thalomid.

195. In a September 28, 2007, internal email (only made publicly available in redacted form in 2018), a Celgene training alert ordered employees "**DO NOT PROCESS THE ORDER**" (emphasis in original) if a generic company calls or writes requesting to order Thalomid. Instead, the call center employees were directed to log the call, advise that a management team member would return the call, and to never transfer the call to someone higher up.

---

[74] Exhibit to MSJ Opp., Dkt. No. 285-1 at PageIDs16246-47.

[75] Exhibit to MSJ Opp., Dkt. No. 286 at PageIDs 18120-21.

196. Employees were further instructed to forward any correspondence via fax to one of their supervisors.

197. Then, on October 18, 2007, Lannett wrote a letter to Mr. Ragland reiterating Lannett's request so that it could conduct BE testing needed to obtain approval to market its generic thalidomide.

198. On January 8, 2008, Celgene advised Lannett that it would not provide samples of Thalomid to Lannett. Rather, Celgene requested Lannett produce voluminous and unnecessary documentation in order for Celgene to "reconsider" the request.

199. On January 14, 2008, Lannett filed a complaint against Celgene seeking, among other things, mandatory injunctive relief requiring Celgene to provide samples of Thalomid as contemplated by the February 12, 2007, FDA letter.[76] The case was dismissed without prejudice.

200. Lannett then provided almost all of the information that Celgene requested except its highly confidential FDA Form 483 inspection reports, which relate to the routine inspection of manufacturing facilities, given that the Thalomid samples Lannett requested would not be used for manufacturing, but rather for BE studies that it would perform overseas.

201. Lannett submitted its proposed study for FDA review and received approval on August 11, 2008.

202. Lannett refiled its complaint on August 15, 2008, alleging violations of the Sherman Act and seeking injunctive relief. Celgene filed its motion to dismiss on November 4, 2008. The motion was denied on May 13, 2010.

203. Celgene reached a confidential settlement with Lannett in 2011.

[76] *Lannett Company, Inc. v. Celgene Corp.*, No. 08-cv-0233. (E.D. Pa.).

204. In its 2012 Annual Report, Lannett stated that "a sizable portion of our fiscal 2013 R&D budget is earmarked for two large market opportunity projects, C-Topical and Thalidomide." Its 2013 Annual Report stated that Lannett "successfully passed critical milestones for submitting a product application for Thalidomide." As discussed below, Lannett eventually filed a thalidomide ANDA in late 2014.

205. Upon information and belief, the settlement between Celgene and Lannett may have contained anticompetitive terms, such as a promise to delay submission of the ANDA.

206. The anticompetitive effect of Celgene's conduct was to delay Lannett's ANDA. Though Lannett began requesting Thalomid samples in 2006, it was unable to obtain such samples due to Celgene's delay until after December 2011 and did not file its ANDA until 2014, at which time Celgene filed a sham patent litigation, discussed below, all to delay Lannett's thalidomide product. As of today, there is no generic thalidomide on the market.

4. Celgene Refused to Sell Samples to Dr. Reddy's.

207. Dr. Reddy's is a prescription drug manufacturer based in Telangana, India. It has been developing generic prescription drugs in the United States since 1994.

208. Dr. Reddy's requested samples of Revlimid from Celgene to perform BE testing in August 2008. Celgene did not reply to this request.

209. Dr. Reddy's repeated its request in December 2008. Celgene offered a single sentence reply in January 2009: "Celgene has no obligation to supply Dr. Reddy's with Revlimid and declines to do so."

210. In their request to Celgene, Dr. Reddy's assured Celgene any testing it performed would comply with FDA guidelines, using methods similar to Celgene's REMS program known as RevAssist to insure proper handling of the subject drugs.[77]

[77] Exhibit to MSJ Opp., Dkt. No. 286-6 at PageIDs 18878-81.

211. Dr. Reddy's filed a citizen petition with the FDA in June 2009, alleging that Celgene was refusing to provide samples to a generic drug manufacturer to perform BE testing.

212. Celgene once again premised its refusal on its REMS program, despite the FDA's previous guidance.

213. In 2016, Dr. Reddy's filed an ANDA for a generic lenalidomide product. As discussed below, Celgene then sued Dr. Reddy's claiming patent infringement.

5. Celgene Refused to Sell Samples to Teva.

214. Teva requested a total of 5,000 Capsules in 5, 10, 15, and 25 mg dosages of Revlimid from Celgene to perform BE testing in March 2009.

215. In their letter to Celgene, Teva stated that its "procedures for conducting any required testing involving lenalidomide and the Revlimid drug product provided by Celgene Corporation will fully comply with FDA requirements. Teva's controls with respect to lenalidomide with be comparable to the RevAssist program."

216. In April of 2009, Celgene responded to Teva's request, and in a one (1) sentence reply, stated "[t]his letter is to inform you that your request for 5,000 capsules of REVLIMID (lenalidomide) in varying strengths is declined."

217. Celgene's refusal to provide Teva with samples of Revlimid follows a similar course of conduct with other generic pharmaceutical companies.

6. Celgene Refused to Sell Samples to Watson.

218. In June of 2009, much like the other generic manufacturers described above, Watson contacted Celgene to acquire samples of Thalomid and Revlimid for BE testing.

219. In its request, Watson assured Celgene the process by which it would handle the samples of these drugs would fully comply with a restricted distribution system similar to RevAssist.

220. Furthermore, Watson assured Celgene that FDA guidelines would be followed, and no drug would be distributed in violation of these guidelines, which would be unlikely to happen given Watson's experience and expertise in the generic drug manufacturing market.

221. In July 2009, despite Watson's assurances that the requested samples would be handled in a safe, effective, and FDA-compliant manner, Celgene responded with a list of 10 pieces of evidence and documentation Watson would need to provide before Celgene would consider Watson's request. Celgene indicated it would respond to Watson's request for Revlimid in a separate letter.

222. Tellingly, Celgene did not say satisfying these 10 requirements would facilitate a prompt sale of the samples, merely that at that time Celgene would "consider" it.

223. Upon information and belief, like the generic manufacturers before and after, Watson was unable to obtain the samples of Thalomid and Revlimid it requested, with no logical reason provided.

7. Celgene Refused to Sell Samples to Sandoz.

224. In May of 2012, much like the other generic manufacturers described above, Sandoz contacted Celgene attempting to acquire samples of Thalomid and Revlimid for BE testing.

225. In response, Celgene refused to provide the samples, and instead listed nine (9) prerequisites Sandoz had to satisfy before it would consider selling the requested samples.

226. These prerequisites included Sandoz provide "Proof of liability insurance sufficient to cover events associated with thalidomide and lenalidomide", "[p]olicies for biohazard handling, disaster recovery plans as well as the storage and use of teratogenic products", and "[w]ritten confirmation that an IND is in effect or a study protocol . . . has been approved by the FDA."

227. Like its correspondence with other generic manufacturers wishing to obtain drug samples, Celgene referenced the REMS procedures as a reason it could not immediately supply Sandoz with samples, despite FDA approval of Sandoz's procedures.

228. Upon information and belief, like the generic manufacturers before it, Sandoz was unable to obtain the samples of Thalomid and Revlimid it requested.

229. Celgene has provided Revlimid and/or Thalomid to no generic manufacturer.

8. Celgene Prevented Barr from obtaining API Supply from Seratec.

230. After the FDA approved Celgene's Thalomid, Barr, a generic drug manufacturer, sought to develop a generic version of thalidomide. As discussed, to market a generic drug, FDA requires a generic manufacturer to file an ANDA application detailing the proposed drug. The ANDA filer must identify its API supplier in its application. The API supplier must submit a Drug Master File ("DMF") to the FDA, which is evaluated with the ANDA.

231. In approximately 2004, Barr succeeded in procuring thalidomide API from Seratec S.A.R.L. ("Seratec"), a French supplier, to develop a generic version of Thalomid by September 2005. Barr submitted its ANDA to the FDA and was waiting to receive a DMF letter from Seratec.

232. Barr's ANDA proposed a skinny label, only seeking approval for ENL, and not MM.

233. While Barr and Seratec were finalizing negotiations, Celgene and Seratec entered an exclusive supply agreement for thalidomide. Upon information and belief, Celgene demanded exclusivity from Seratec to interfere with Barr's ability to market generic Thalomid. The exclusivity agreement was not because Celgene required all the API that Seratec could produce.

Seratec, therefore, could no longer supply Barr with its thalidomide API. The FDA did not accept Barr's ANDA due to deficiencies in providing a DMF from Seratec.[78]

234. Consequently, Barr was forced to find a different thalidomide supplier and repeat testing, causing it great expense and delay in launching generic thalidomide.

235. On February 27, 2006, Celgene's competitive intelligence firm, GBMC, updated Celgene that Barr completed BE testing and was planning on filing a thalidomide ANDA in the second quarter of 2006 using API from either Antibioticos of Italy or Shilpa of India. GBMC noted that "[t]hese companies were being used to replace the Seratec API that Barr originally was using for its ANDA."

236. After securing a new supplier and performing new BE studies and validation testing, Barr submitted its thalidomide ANDA on September 22, 2006. The ANDA showed that Barr's generic product was bioequivalent to Celgene's Thalomid. The FDA accepted Barr's thalidomide ANDA for filing on December 4, 2006.

237. Celgene subsequently initiated a patent infringement lawsuit against Barr for its thalidomide ANDA, as discussed more thoroughly below, initiating an automatic 30-month stay of FDA's approval of Barr's ANDA.

238. GBMC predicted that Barr could be expected to receive FDA approval of its thalidomide ANDA in the first quarter of 2009.

[78] It was unclear to Celgene how Barr acquired Thalomid samples for BE testing in 2005. In Celgene's response to interrogatories in a separate litigation recently made public, Celgene noted "Celgene informed the FDA of its belief that Barr had acquired Thalomid® capsules from a pharmacy in Astoria, New York in violation of the requirements of the S.T.E.P.S.® program. The FDA informed Celgene that it did not intend to 'recapture' these capsules from Barr, and that the manner in which Barr obtained Thalomid® for use in its bioequivalency testing would not affect FDA's consideration of any subsequent ANDA with respect to thalidomide that Barr might file."

239. In a May 2009 email between executives at Celgene, which contained the minutes of a previously held internal meeting, these executives discussed Barr's attempt to market generic thalidomide in the USA.[79]

240. According to the minutes of the meeting: "Dianne Azzarello, Regulatory Canada discussed possible ways to defend Thalidomide against generic infiltration in the USA. From her experience in working with generic drug providers, she is of the opinion that we are able to use bioequivalence as generic defence strategy. The team supports this notion. If generic companies have to effectively prove that they are at least equivalent to what Celgene has to offer (incl. Celgene's RiskMAP) before making product available on the market."

241. They also discussed paying for research and publishing research papers stating generic manufacturers' version of Thalomid were not bioequivalent: "Diane Azzarello and Henry Lau are working with Dr. Iain McGilveray who will publish a paper providing evidence that many other formulations of thalidomide available are not bio equivalent to Celgene's Thalomid. We may also include our simple formulation and its chemical properties as rationale. Funding for this publication is estimated to be $40k $60k."

242. These internal discussions are further evidence Celgene was not negotiating the sale of sample drugs to generic manufactures in good faith and were instead employing delay tactics at every turn to resist supplying generic manufactures with the requested drugs.

iii. Celgene Had No Legitimate Business Justifications for Refusing Samples To Would Be Competitors Because It's Safety Concerns Were Pretextual.

243. While Celgene refused to supply any potential ANDA sponsor the necessary and required samples of Revlimid and/or Thalomid based on safety concerns, it authorized its

[79] Exhibit to Brief in Further Support of Motion for Summary Judgment, *Mylan Pharmaceuticals, Inc. v. Celgene Corp.*, No. 2:14-cv-02094-ES-MAH (D.N.J. Mar. 20, 2018) ("MSJ Reply Papers"), Dkt. No. 284-4 at PageIDs 16101-4.

competitive intelligence firm to purchase, handle, and transfer thalidomide with no safety training required.

244. In 2003, Celgene authorized GBMC to purchase thalidomide API from a European supplier, Alan Pharmaceuticals. In fact, GBMC was authorized by Celgene to use undercover purchases to obtain samples of thalidomide API from various API suppliers. In an undated letter, GBMC detailed the sequence of events it used to acquire, at Celgene's request, thalidomide samples outside the normal chains of distribution. This sequence included falsifying prescriber names and permitting GBMC (a non-pharmaceutical company with no experience in handling teratogenic drug product) to handle thalidomide samples, all without a formal tracking mechanism. Celgene's Senior Director of Market Research testified in a previous litigation that he did not notify Celgene's legal department of these undercover purchases, that Celgene did not do background checks on individuals that would be handling the drug product, and that he could not recall whether the purchased product was in its proper packaging when Celgene received it, or who at Celgene received it.

245. The Celgene-authorized transactions did not comport with any safety protocol.

246. Celgene willingly and frequently provided access to Thalomid and Revlimid to non-competitor research organizations, outside the REMS process and without FDA guidance or approval for the safe handling of the drug products, for the purpose of conducting clinical studies.

247. Celgene provided Revlimid for at least 3,600 different research and investigational studies that all operated outside the REMS process. Celgene similarly provided Thalomid for over 100 investigator-initiated trials ("IIT").[80]

248. For example, Celgene provided Thalomid and Revlimid to the Johns Hopkins School of Medicine for clinical trials and provided Revlimid to Intergroupe Francophone du

[80] IITs are clinical studies initiated and managed by non-pharmaceutical company researchers, such as individual investigators, institutions, collaborative study groups, cohorts or physicians.

Myelome, University Hospital of Toulouse, and Groupe Francophone Des Myelodysplasies, as well as the National Cancer Institute, Eastern Cooperative Oncology Group, Mayo Clinic, and MD Anderson Cancer Center in Houston, Texas.

249. An IIT process is initiated when an investigator submits a Letter of Intent ("LOI") outlining a proposal. The brand company, here Celgene, then reviews the proposal. Celgene testified that it tried not to review the full protocol, but rather would typically review a simplified synopsis, along with the nature of the request, the budget, and the amount of drug requested. The request, typically adjudicated within two (2) months, does not require in-house counsel assistance. Celgene has never denied an IIT proposal due to fetal exposure safety concerns.

250. After approving an IIT proposal, Celgene works with the investigator to draft a study protocol and consent form which then is submitted to the FDA for approval. Celgene had admitted that FDA's approval gives Celgene confidence in the safety of the trial. Celgene then supplies Revlimid or Thalomid to the investigator to initiate the study.

c. Celgene Commits Fraud on the USPTO and Files Sham Litigations Seeking to Enforce its Fraudulently Obtained Patents.

251. Even when a generic manufacturer managed to obtain a sample of Thalomid or Revlimid, Celgene was still able to unlawfully block them from the market by obtaining numerous redundant patents related to the composition, and plans for safe distribution, of Thalomid and Revlimid. Celgene's construction of a patent fortress was part of its multifaceted and decades-long scheme to monopolize the markets for Thalomid and Revlimid.

252. These types of patents generally claim the use of registries to register patients, prescribers, and pharmacies, testing and regular re-testing the patient for signs of harmful side effects associated with the drug (including pregnancy testing), counseling patients about the risks associated with the drug, limiting the dispensed amount of the drug, and prescribing and dispensing the drug after analyzing the risk and determining that it is acceptable.

253. The patent on Celgene's active ingredient in Revlimid, the '517 Patent, expired in 2019. The last of Revlimid's patents listed in the Orange Book, the '800 Polymorph patent, expires in 2028.

254. Celgene, armed with its fraudulent patents, serially filed sham patent infringement lawsuits and citizen petitions against any Paragraph IV ANDA filer. Through these serial sham litigations, Celgene was able to successfully, and illegally, block generic entrants from the Revlimid and Thalomid markets.

i. Celgene's Fraudulent Patent Prosecution

1. Celgene Failed to Disclose Material Information on Patentability of the Drug Composition Patents.

255. The original, core patent for the composition of Celgene's thalidomide-derived drugs is the '517 Patent, filed in 1996. Thalidomide, the drug on which Revlimid is based, was first on the market in 1957. The innovations on which the '517 Patent is based are obvious in light of the innovations and research conducted long before Celgene began its effort to bring Thalomid and Revlimid to market; thus, the '517 Patent and the subsequent patents derived from it are invalid.

256. Thalidomide was found to be immunotherapeutic in the 1960's, meaning it was known that thalidomide could treat diseases by inducing, enhancing or suppressing an immune response. Extensive scientific literature establishes the immunomodulatory properties of thalidomide and its derivative, lenalidomide, the active ingredient in Revlimid. It was well established that thalidomide has immunomodulatory properties, that thalidomide derivatives have the same immunomodulatory properties as thalidomide, that thalidomide was effective in the treatment of autoimmune diseases, that thalidomide derivatives inhibited Tumor Necrosis Factor Alpha, and that thalidomide is an angiogenesis inhibitor which also aids in the treatment of multiple myeloma. There has been nothing unexpected or unanticipated about the effects or uses

of Thalomid or Revlimid over the precedent scientific literature. In filing the '517 Patent with the USPTO, none of these precedents were cited by Celgene. The USPTO examiners were not aware of key prior art when the '517 Patent was granted.

257. In 2003, Celgene filed the '012 Patent for thalidomide, a drug that had first been used almost half a century prior. Again, none of the relevant precedent above was cited in the USPTO filing by Celgene. Under 37 CFR 1.56, Celgene had a duty to disclose information material to patentability. Patents will be revoked, and applications will be denied if this duty of disclosure was violated through bad faith or intentional misconduct. For the drug composition patents, as well as the distribution patents discussed below, Celgene has shown a pattern of omitting important precedents in USPTO filings for Thalomid and Revlimid.

a. Celgene Tried to Extend its Monopoly by Filing Redundant Drug Composition Patents Based on Previously Ill-Gotten Patents.

258. In an effort to extend their monopoly on the sale of thalidomide derivatives, Celgene began filing additional patents on the polymorphic forms of lenalidomide. Polymorphs, also known as solvates or crystalline forms, of previously patented compounds are routinely developed as a standard practice in the pharmaceutical industry, according to a US patent examiner in a rejection of one of Celgene's polymorph patent applications, and generally not separately patentable.

259. However, Celgene managed to get the Polymorphs patents approved by the USPTO and filed in the FDA Orange Book, the '800 Patent and the '217 Patent, which expire in 2027 and 2024, respectively. Since these patents have the latest expiration dates of any patents associated with Thalomid or Revlimid, they have been key patents cited in repeated attempts by Celgene to block generic competitors from the market. Celgene routinely cites these Polymorph patents against generic manufacturers that have filed generic Thalomid and/or Revlimid ANDAs.

260. In doing so, Celgene has also repeatedly left open the Polymorph patents to charges of invalidity and has repeatedly settled instead of testing the strength of these patents in court for fear of the result. When Natco Pharma Limited ("Natco Pharma") filed an ANDA for its generic version of lenalidomide, Celgene brought suit against it, Watson, and Arrow International Ltd., ("Arrow") (collectively, "Natco") claiming infringement.[81] The parties agreed to a Markman hearing to settle the meaning of disputed terms in the patent. Citing Celgene's own clarified definition of the term "hemihydrate," Natco amended its invalidity contentions to the '800 patent, arguing that that it was invalid for indefiniteness, lack of enablement and lack of written description. When Celgene was unable to prevent Natco from raising these amended invalidity contentions, Celgene quickly settled with Natco, allowing Natco market share prior to the expiration of the patents rather than let its Polymorph patents face invalidation. Having learned a dangerous lesson, Celgene did what was necessary to avoid a similar Markman hearing over the meaning of "crystalline" in its subsequent litigation against Dr. Reddy's.[82]

261. Celgene knows that the overbroad terms of its redundant Polymorph patents are an attempt to block generic competitors from bringing non-infringing products to market where the generic manufacturer has developed a suitable workaround to Celgene's patents. The claims of Celgene's other Polymorph patent, the '217 Patent, also call out crystalline and hemihydrate forms, and are invalid for the same reasons as the '800 patent. These patents, like the '517 Patent from which they were derived, were obtained due to a failure to disclose publicly available prior art and

[81] *Celgene Corp. v. Natco Pharma Ltd.*, No. 10-5197, 2015 WL 4138982 (D.N.J. Jul. 9, 2015). Celgene alleged that while Natco Pharma filed the ANDA, Arrow assisted Natco Pharma in preparing and filing the ANDA, and Watson prosecuted the ANDA before the FDA.

[82] Letter to Court, *Celgene Corp. v. Dr. Reddy's Laboratories Ltd.*, 2:16-cv-7704 (D.N.J. Mar. 23, 2018), ECF Dkt. No. 77. On the date that its responsive Markman pleadings were due, Celgene filed a letter informing the court that it resolved its claim construction disputes with Dr. Reddy's and would not be filing responsive pleadings.

research from decades earlier, which anticipate and invalidate the patent. Celgene's failure provides an independent basis for invalidity. These polymorphs are also obvious variants of the composition of matter patent, adding further basis for invalidity. Finally, based on Celgene's own representations in the Markman hearing that was held in the *Natco* litigation, the claims of the patent are unenforceable as overbroad.

262. The anticompetitive effect of Celgene's conduct with respect to the composition patents was to erect a fortress of protection for Celgene's continued monopoly.

2. Celgene Failed to Disclose Material Information on Patentability of The Distribution Method Patents.

263. As discussed above, in 1998, Celgene only listed the '501 Patent in the Orange Book in connection with Thalomid. Since then, it has listed numerous additional patents, including the '720, '976, '977, and '784 patents (together with the '501 Patent, the "Distribution Method Patents") in the Orange Book in connection with Thalomid.

264. The '501 and '720 patents were invalidated by the Patent Trial and Appeal Board ("PTAB") on October 26, 2016.[83]

265. The PTAB found the '501 Patent invalid as obvious over the combined disclosures of three (3) asserted prior art references as representative of the level of ordinary skill in the art.

266. Guidance regarding the clinical use and dispensing of thalidomide was provided by an existing publication in 1994 that identified a patient subpopulation of women who could and

[83] See *Coalition for Affordable Drugs VI LLC, et al., v. Celgene Corp.*, IPR2015-01092, Paper No. 73 (P.T.A.B. Oct. 26, 2016), https://portal.unifiedpatents.com/ptab/case/IPR2015-01092; IPR2015-01096, Paper No. 73 (P.T.A.B. Oct. 26, 2016), https://portal.unifiedpatents.com/ptab/case/IPR2015-01096; IPR2015-01102, Paper No. 75 (P.T.A.B. Oct. 26, 2016), https://portal.unifiedpatents.com/ptab/case/IPR2015-01102; IPR2015-01103, Paper No. 76 (Oct. 26, 2016), https://portal.unifiedpatents.com/ptab/case/IPR2015-01103 ("*Coalition*").

wished to become pregnant, warning that they should not be treated with Thalomid, and recommending counseling on the risks of thalidomide as well as the use of contraception.[84]

267. Further guidance was also provided by the existing pregnancy-prevention program for women users of Accutane, a Vitamin A analogue of isotretinoin and a known teratogenic drug. Accutane was subject to a program of preventative measures, such as pregnancy-risk warnings on packaging, targeting of women of childbearing age for the pregnancy-prevention program, and communication between physicians and patients regarding the drug's teratogenic risk and the need to prevent pregnancy.[85]

268. Guidance for the use of a national database to register prescribers, pharmacies, and patients as a way to restrict access to drugs that could be potentially hazardous was also published well before the '501 Patent was filed, such as the nation-wide registry for patients requiring clozapine, a potent anti-psychotic drug with potential for serious side effects.[86]

269. The PTAB found that a person of ordinary skill in the art would have understood how to implement Powell's teachings in clinical and pharmacy settings in view of the Accutane Pregnancy Prevention Program and the Clozaril (clozapine) controlled distribution model outlined in Dishman. The PTAB was not persuaded by Celgene's argument that the prior art did not specifically single out men who could impregnate a woman as a subgroup, noting that a skilled artisan would have recognized that the sperm of male patients could be damaged by teratogenic drugs and consequently result in birth defects if the male was to impregnate a female.[87]

---

[84] R.J. Powell and J.M.M Gardner–Medwin, *Guideline for the clinical use and dispensing of thalidomide*, POSTGRAD MED. J. 70, 901–904 (1994) ("Powell").

[85] Allen A. Mitchell et al., *A Pregnancy–Prevention Program in Women of Childbearing Age Receiving Isotretinoin*, NEW ENG. J. MED. 333:2, 101–06 (Jul. 13, 1995) ("Mitchell").

[86] Benjamin R. Dishman et al., *Pharmacists' role in clozapine therapy at a Veterans Affairs medical center*, AM. J. HOSP. PHARM. 51, 899–901 (Apr. 1, 1994) ("Dishman").

[87] *Coalition,* IPR2015–01092, Paper No. 73.

270. The PTAB found the '720 Patent invalid as obvious over the combined disclosures cited against the '501 Patent for the original S.T.E.P.S. program, while finding that the inherent dangers of Thalidomide would drive someone of ordinary skill in the art to proactively improve the system. Citing U.S. Patent No. 5,832,449 (issued Nov. 3, 1998, "Cunningham"), which describes an approval code used by prescribers and pharmacies to track and manage pharmaceutical products, the PTAB found that a person of ordinary skill in the art could predict that such an approval code could be utilized by prescribers and pharmacies to track and manage Thalomid and Revlimid. In light of this prior art, the PTAB invalidated the '720 patent as obvious.

271. As the PTAB noted, "[w]hen it benefitted [Celgene's] interests before the FDA, [Celgene] freely admitted that its 'plan [for thalidomide] is built on experience with restrictions on such other drugs with severe adverse effects as Accutane … and Clozaril."[88] Before the USPTO however, Celgene repeatedly failed to disclose the very materials that it relied on in presenting its program to the FDA, along with other similar prior art such as the Clozaril Patient Monitoring Service and numerous published works describing the features of REMS programs similar to Celgene's original and modified S.T.E.P.S. programs.

272. On July 30, 2019, the Federal Circuit affirmed the findings of the PTAB invalidating the '501 and '720 patents for obviousness.

273. The '976 Patent, the '977 Patent, and the '784Ppatent, filed more than three years later, are nearly identical to the invalidated '501 and '720 patents. In fact, many of these patents were so similar that Celgene did not even bother changing the title or abstract describing the patent.

274. Celgene also listed the '886 Patent in the Orange Book in connection with Thalomid on November 20, 2012.

[88] IPR2015-01092, at 24 (P.T.A.B. Oct. 26, 2016).

275. Celgene listed each of these patents in the Orange Book for both Thalomid, and later Revlimid, with full knowledge that protocols for the safe distribution of dangerous drugs like Thalomid and Revlimid have been in public use for years before Celgene filed any of its patent applications.

276. The Distribution Method Patents were obtained from the USPTO through knowing and willful fraud and are unenforceable. Celgene caused these patents to be listed in the Orange Book with knowledge that they were fraudulently obtained and are unenforceable. Celgene's withholding of material information on patentability with the intent to deceive the USPTO was done for the anticompetitive purpose of excluding generic competitors and maintaining a market monopoly.

277. The public prior use and/ or publication of Celgene's claimed "Distribution Method" inventions include:

a. The Clorazil Patient Monitoring Service ("CPMS")

278. The CPMS is a program for the distribution of Clorazil™. Clorazil is used to treat individuals with schizophrenia. A major side effect of Clorazil is agranulocytosis, a potentially fatal blood disorder.

279. Clorazil is distributed through the CPMS, which uses a national registry for patients, prescribers, and pharmacies. This registry identifies and reduces the risk of Clorazil-related complications.

280. The CPMS uses a computerized registry that includes patient information such as white blood cell counts to determine risk factors. The CPMS also tests white blood cell counts prior to starting Clorazil therapy. The CPMS mandates prescribing and dispensing only a limited supply of Clorazil after the prescriber determines that the risk is acceptable and provides the dispensing pharmacy with a report containing white blood cell counts and the doctor's opinion that the patient is eligible to receive required Clorazil. Additionally, the CPMS contains protocols for

discontinuing treatment if the doctor determines, based on weekly blood tests, that the risk becomes unacceptable. Weekly refills are only provided after the same criteria for the initial dispensation are met again at the start of each week.

281. The CPMS qualifies as prior art to the claims of the Distribution Method Patents and the '886 Patent under 35 U.S.C. § 102(b), because it was commercially used in the United States more than one (1) year before the earliest priority date of the Distribution Method Patents and the '886 Patent.

282. The applicants of those patents, their agents, and/or their attorneys did not disclose the CPMS to the USPTO during pendency of the applications from which the Distribution Method Patents issued.

b. Honigfeld, "Effects of the Clozapine National Registry System on Incidence of Deaths Related to Agranulocytosis," *Psychiatric Services*, 47(1):52-56 (1996) ("Honigfeld I")

283. Honigfeld I describes details of the CPMS and qualifies as prior art to the Distribution Method Patents and the '886 Patent under 35 U.S.C. § 102(b), because it was publicly available and accessible more than one (1) year prior to the earliest priority date of the Distribution Method Patents and the '886 Patent.

284. The applicants, their agents, and/or their attorneys did not disclose the Honigfeld I to the USPTO during the pendency of the applications from which the Distribution Method Patents issued.

c. Honigfeld, *et al*., "Reducing Clozapine-Related Morbidity and Mortality: 5 Years of Experience with the Clozaril National Registry," J. *Clin. Psychiatry* 59 (suppl 3): 3-7 (1998) ("Honigfeld II")

285. Honigfeld II also details the protocols of the CPMS and qualifies as prior art to the '501 and '976 patents under 35 U.S.C. § 102(a) because it was publicly available information prior

to the earliest priority date of the '501 and '976 patents. Honigfeld II qualifies as prior art to the '720, '977, '784, and '886 patents under 35 U.S.C. § 102(b), because it was publicly available information more than one (1) year prior to the earliest priority date of the '720, '977, '784, and '886 patents.

286. The applicants, their agents, and/or their attorneys did not disclose Honigfeld II to the USPTO during the pendency of the applications from which the Distribution Method Patents issued.

d. The "Guide to the Clozaril Patient Monitoring Service," Novartis Pharmaceuticals UK Ltd. (Nov. 1997) ("The Guide")

287. Details of the CPMS are described in the Guide, which qualifies as prior art to the '501 and '976 patents under 35 U.S.C. § 102(a) because it was publicly available prior to the earliest priority date of the '501 and '976 patents. The Guide qualifies as prior art to the '720, '977, '784, and '886 patents under 35 U.S.C. §102(b), because it was publicly available more than one (1) year prior to the earliest priority date of the '720, '977, '784, and '886 patents.

288. The applicants, their agents, and/or their attorneys did not disclose the Guide to the USPTO during the pendency of the applications from which the Distribution Method Patents issued.

e. The ACCUTANE® Pregnancy Prevention Program ("PPP")

289. The PPP is a program for the distribution of Accutane, known generically as isotretinoin. The PPP was developed and implemented to prevent fetal exposure to isotretinoin. The PPP included an information package for physicians warning of the risks of dispensing the drug to pregnant women, a patient informed consent form containing warnings detailing the risks associated with Accutane and the requirements to receive Accutane and required pregnancy testing

and birth control counseling before the patient started a course of Accutane therapy. It also required a patient survey on compliance.

290. The PPP qualifies as prior art to the claims of the Distribution Method Patents and the '886 Patent under 35 U.S.C. § 102(b), because it was commercially used in the United States more than one (1) year prior to the earliest priority date of the Distribution Method Patents and the '886 Patent.

291. The applicants, their agents, and/or their attorneys did not disclose the PPP to the USPTO during the pendency of the applications from which the Distribution Method Patents and the '886 Patent issued.

f. The Accutane PPP Package, a 1994 patent and prescriber information package for Accutane, distributed by Roche Pharmaceuticals ("PPP Package")

292. The PPP Package described details of the PPP. It qualifies as prior art to the Distribution Method Patents and the '886 Patent under 35 U.S.C. § 102(b), because it was publicly available more than one (1) year prior to the earliest priority date of the Distribution Method Parents and the '886 Patent.

293. The applicants, their agents, and/or their attorneys did not disclose the PPP Package to the USPTO during the pendency of the applications from which the Distribution Method Patents and the '886 Patent issued.

g. A Centers for Disease Control public meeting entitled "Preventing Birth Defects Due to Thalidomide Exposure" and transcript from March 26, 1997 "The CDC Meeting and Transcript"

294. On March 26, 1997, the CDC held a public meeting to discuss thalidomide and its associated risks. The meeting was attended by at least two Celgene employees: Dr. Jerome Zeldis,

the then Vice President of Medical Affairs at Celgene, and Mr. Bruce A. Williams, a named inventor for the Distribution Method Patents and the '886 Patent.

295. The transcript of the CDC Meeting shows that the PPP and the CPMS were discussed, as was the use of the protocols in those two systems in designing a similar protocol for thalidomide.

296. The CDC Meeting attendees discussed potential elements to be part of a thalidomide distribution program, including: (1) patient, pharmacy, and prescriber registration; (2) counseling patients about the risks of thalidomide and the need for contraception; (3) required pregnancy testing before thalidomide is prescribed; (4) monthly testing thereafter; (5) providing proof that the patient is not pregnant before the drug can be dispensed and providing contraceptives with the drug; (6) limiting the length of the prescription to a monthly supply; and (7) requiring return to the prescriber before refilling the prescription.

297. The CDC Transcript was publicly available under the Freedom of Information Act more than one (1) year prior to the earliest priority date of the Distribution Method Patents and the '886 Patent. It therefore qualifies as prior art to the Distribution Method Patents and the '886 Patent under 35 U.S.C. § 102(b).

298. The applicants, their agents, and/or their attorneys did not disclose the CDC Meeting or the CDC Transcript to the USPTO during the pendency of the applications from which the Distribution Method Patents and the '886 Patent issued.

h. Zeldis, *et al*., "S.T.E.P.S.™: A Comprehensive Program for Controlling and Monitoring Access to Thalidomide," *Clinical Therapeutics* 21(2): 319-30 (1999) ("Zeldis")

299. Zeldis qualifies as prior art to the '720, '977, and '784 patents under 35 U.S.C. § 102(b), because it was publicly available more than one (1) year prior to the earliest priority date of the '720, '977, and '784 patents.

300. Zeldis is co-authored by Celgene employees, including Zeldis and named inventor Williams. It described the S.T.E.P.S. program developed by Celgene, with the guidance of the FDA, to monitor and control access to thalidomide. Zeldis states that the S.T.E.P.S. protocol is "based in part on experience gained with other drugs—specifically isotretinoin and clozapine— that offer important clinical benefits but carry the potential for serious harm."

301. Zeldis states:

> Celgene has incorporated elements of both these successful programs into the S.T.E.P.S.™ program for controlling the distribution of thalidomide. Educational materials for patients and physicians and label warnings similar to those used in the isotretinoin program are coupled with clinician and patient registration and testing similar to those used in the clozapine program.

302. Zeldis cites Honigfeld I and Honigfeld II in its discussion of Clorazil.

303. The applicants, their agents, and/or their attorneys did not disclose Zeldis to the USPTO during the pendency of the applications from which the Distribution Method Patents issued.

i. The September 4 and 5, 1997 Center for Drug Evaluation and Research of the Food and Drug Administration public meeting ("The CDER Meeting and Transcript")

304. The September 4-5, 1997, CDER Meeting was recorded in a publicly-available transcript and at least seven (7) Celgene employees, including named inventor Bruce Williams who made a presentation on preventing fetal exposure to thalidomide, attended the meeting.

305. Williams stated:

> [w]e recognize that there may be some models in the marketplace today which could serve as at least a starting point in our thinking as we develop this program. Two of them came to mind that I would like to just speak very briefly to, to indicate why we feel that they are relevant models, but also where we feel they may not go far enough for this particular circumstance. The first is one that this committee, particularly, is very

> familiar with. And that is Roche's Accutane, used to treat severe acne, and known to be a human teratogen.

306. Williams described the Accutane system, the PPP, and its purported drawbacks, which he described as a lack of a mandatory registry and an inability for a pharmacist to determine at dispensing whether the patient has participated in Roche's program.

307. He noted that the PPP's purported drawbacks drove Celgene to analyze the CPMS protocol, to which he stated:

> In looking at how Sandoz structured this [Clozaril] system, we began to see that by taking elements from the Roche program [Accutane], elements from the Clozaril program and other unique elements, we would create a system that really would be state of the art, represent a significant step, we believe, forward in the ability to make drugs like thalidomide available to patients who need it, while at the same time providing a very high margin for protection.

308. The CDER Transcript qualifies as prior art to the Distribution Method Patents and the '886 Patent under 35 U.S.C. § 102(a), because it was publicly available under the Freedom of Information Act prior to the earliest priority date of the Distribution Method Patents and the '886 Patent. The CDER Transcript also qualifies as prior art to the '720, '977, and '784 patents under 35 U.S.C. § 102(b), because it was publicly available information under the Freedom of Information Act more than one (1) year prior to the earliest priority date of the '720, '977, and '784 patents.

309. The applicants, their agents, and/or their attorneys did not disclose the CDER Transcript to the USPTO during the pendency of the applications from which the Distribution Method Patents issued.

j. The September 9 and 10, 1997 public workshop held by the National Institutes of Health, FDA, and CDC, entitled "Thalidomide: Potential Benefits and Risks, Open Public Scientific Workshop" ("The NIH Meeting and Transcript")

310. The NIH Meeting on September 9-10, 1997 was recorded in a publicly available transcript. There, named inventor Williams gave a presentation regarding a Celgene proposal "for a distribution and education system" for thalidomide.

311. Williams stated:

> when we started in this endeavor we looked to see what else was in the marketplace that might serve as a model. We accepted that we were unlikely to find any single model that carried all of the elements that would likely be necessary for this drug, but we did find two that in part covered many of the elements that might be required. Accutane, we heard about yesterday. Comprehensive educational program, counseling, and good contraception, informed consent, a package with integrated product warnings, and a surveillance system, albeit voluntary. Many elements that clearly with either change or updating or enhancement would likely be relevant to what needed to be done for thalidomide. We also heard about the Novartis program for Clozaril, a drug used to treat schizophrenia and introduced in an era where existing antischizophrenia drugs were not particularly effective for many patients. In addition, they carried their own baggage of side effects. However, in a small proportion of patients who take this drug, a granular cytosis [sic] can develop in a very short period of time.

312. The NIH Transcript qualifies as prior art to the Distribution Method Patents and the '886 Patent under 35 U.S.C. § 102(a), because it was publicly available under the Freedom of Information Act before the earliest priority date of the Distribution Method Patents and the '886 Patent. The NIH Transcript also qualifies as prior art to the '720, '977, and '784 patents under 35 U.S.C. § 102(b), because it was publicly available and accessible under the Freedom of Information Act more than one (1) year prior to the earliest priority date of the '720, '977, and '784 patents.

313. The applicants, their agents, and/or their attorneys did not disclose the NIH Meeting or Williams' presentation at the NIH Meeting to the USPTO during the pendency of the applications from which the Distribution Method Patents issued.

314. Each of the above enumerated publications, meetings, or programs constitutes prior art that Celgene was required to disclose but failed to disclose to the USPTO, for each of the Distribution Method Patents.

315. In its 2010 application for the '886 Patent, Celgene failed to disclose the existence of the PPP Package or the CDC Transcript. Had Celgene disclosed the PPP Package or the CDC Transcript, the USPTO would not have issued Celgene the '886 Patent.

k. The Distribution Method Patents are Unenforceable.

316. All the above prior arts are material to the patentability of the Distribution Method Patents. They firmly establish, *prima facie*, unpatentability under 35 U.S.C. §§ 102 and 103. Each prior art listed is material to the patentability of the Distribution Method Patents because, but for Celgene's failure to disclose them, the USPTO would not have allowed any or all of the claims of the Distribution Method Patents to issue.

317. All the above prior arts are material to the patentability of the Distribution Method Patents because, individually and/or taken together, they contradict or are inconsistent with positions the applicants took in opposing arguments of unpatentability relied on by the USPTO or asserting arguments of patentability.

318. All of the above prior arts are material to the patentability of the Distribution Method Patents because, individually and/or taken together, they constitute information that a reasonable Examiner reviewing the applications would consider material in determining whether to allow the proposed claims to issue.

319. The applicants of the Distribution Method Patents, their agents, and/or their attorneys and anyone else substantively involved in the application, owed a duty of good faith and candor to the USPTO during the pendency of the applications from which the Distribution Method Patents issued. Pursuant to that duty, they were required to disclose all information material to the applications from which the Distribution Method Patents issued.

320. During the pendency of the applications from which the Distribution Method Patents issued, the applicants, their agents, attorneys, and anyone else substantively involved in the application, owed a duty of good faith and candor to the USPTO during the pendency of the applications from which the Distribution Method Patents issued. Pursuant to that duty, they were required to disclose all information material to the applications from which the Distribution Method Patents issued.

321. While the applications from which the Distribution Method Patents issued were pending, the applicants, their agents, attorneys, and anyone else substantively involved in the prosecution were aware of the above listed prior arts and knew that they were material to those applications.

322. The Distribution Method Patents applicants, their agents, attorneys, and anyone else substantively involved in the prosecution withheld the above listed prior arts with the intent to deceive the Patent Examiner.

323. The Distribution Method Patents applicants, their agents, attorneys, and anyone else substantively involved in the prosecution knowingly and willfully misrepresented and omitted material information during the pendency of the applications from which the Distribution Method Patents issued. But for these misrepresentations and omissions, the Distribution Method Patents would not have issued.

324. The Distribution Method Patents were obtained from the USPTO through knowing and willful fraud; accordingly, they are unenforceable.

325. The Supreme Court's decision in *Alice Corp. v. CLS Bank International*,[89] after the distribution method patents were issued, has raised doubts that REMS patents are even patentable subject matter at all. In its decision, the Court created a new test for patents that are directed to

[89] *Alice Corp. Pty. Ltd. v. CLS Bank International, et al.*, 573 U.S. 208 (2014).

abstract ideas, such as a strategy for distribution, in which the court will examine the elements of the claim to determine whether it contains an 'inventive concept' that is enough to 'transform' the abstract idea in the claims enough to make it eligible for patent protection. Simply performing a process that has been done before, such as safely dispersing prescriptions, and performing it on a computer does not transform an abstract idea into patentable subject matter. Since *Alice,* patents for REMS distribution methods have been invalidated as unpatentable abstract ideas.[90]

326. Celgene caused the Distribution Method Patents to be listed in the Orange Book with knowledge that they were fraudulently obtained from the USPTO and are unenforceable. Celgene listed the Distribution Method Patents in the Orange Book with the intent and purpose of impeding thalidomide and lenalidomide ANDA filings and delaying FDA approval of any ANDAs for at least thirty (30) months pursuant to 21 U.S.C. § 355 (j)(5)(B)(iii).

l. Celgene Tried to Extend Its Monopoly by Filing Redundant Distribution Method Patents Based on its Previously Ill-Gotten Patents.

327. Celgene applied for another patent, the '886 Patent, on December 13, 2010, just after Barr and Natco each filed an ANDA for thalidomide. Celgene's patent application did not disclose the PPP Package or the CDC Transcript as prior art.

328. Both the PPP Package and the CDC Transcript are material to the patentability of the '886 Patent. These two (2) prior arts contradict or are inconsistent with positions the applicants took in opposing arguments of unpatentability relied on by the USPTO or asserting arguments of patentability. They are also material because they constitute information that a reasonable Examiner would consider important in deciding whether to allow the proposed claims of the '886

[90] *See Par Pharmaceutical, Inc., et al., v. Jazz Pharmaceuticals, Inc.,* IPR2015-00554, Paper No. 68 (P.T.A.B. July 27, 2016) for patent 7,668,730 previously held by Jazz Pharmaceuticals, https://portal.unifiedpatents.com/ptab/case/IPR2015-00554.

Patent to issue. Had the USPTO been aware of those undisclosed prior art references, the USPTO would not have allowed any or all of the claims of the '886 Patent to issue.

329. Celgene obtained the '886 Patent on November 20, 2012, through knowing and willful fraud. It is therefore unenforceable. Celgene further caused the '886 Patent to be listed in the Orange Book with knowledge that it was fraudulently obtained from the USPTO and is unenforceable. Celgene acted with the intent to thwart or otherwise discourage generic manufacturers from filing thalidomide and/or lenalidomide ANDAs, and to delay FDA approval of any such ANDA for at least thirty (30) months pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

330. The applicants of the '886 Patent, their agents, attorneys, and anyone else substantively involved in the prosecution owed a duty of good faith and candor to the USPTO during the pendency of the applications from which the '886 Patent issued. As part of that duty of candor, they were required to disclose information material to the application from which the '886 Patent issued.

331. During the pendency of the application from which the '886 Patent issued, the applicants, their agents, attorneys, and anyone else substantively involved in the prosecution were aware of the PPP Package and the CDC Transcript, knew that that these two (2) prior arts were material to that application and withheld them with the intent to deceive the Patent Examiner. But for these omissions and misstatements, the '886 Patent would not have issued.

3. Celgene Attempted to Extend Its Monopoly by Filing Redundant Dosing Patents and Failed to Disclose Material Information on Patentability of the '745 Patent.

332. Celgene filed the '745 Patent for methods and compositions for inhibition of angiogenesis in 2006, listing Robert D'Amato as inventor. D'Amato had filed and was granted the 5,593, 990 (the "'990 Patent") patent for methods and compositions for inhibition of angiogenesis in 1995, along with several other patents relating to thalidomide analogs, based on his research

with The Children's Medical Center Corporation ("CMCC") in Boston. Around this same time, Celgene was beginning to file its initial patents for thalidomide analogs, which resulted in Celgene and the company to whom CMCC had licensed its patents, EntreMed, suing each other for infringement and challenging the validity of the other's patents.[91] This dispute was resolved in 2002 when the parties entered into an exclusive license agreement allowing Celgene a worldwide, exclusive license in CMCC's entire portfolio of thalidomide analog patents in exchange for paying royalties.

333. When Celgene filed for the '745 Patent, it did not cite the '990 Patent or any of the other D'Amato dosing patents that they held the exclusive license for that dealt with treating disease states resulting from angiogenesis. The addition that anti-inflammatory drugs and NSAIDS can inhibit angiogenesis alone or in combination with thalidomide and its analogs was already disclosed by prior art. Celgene filed this redundant patent in an attempt not only to extend its monopoly but to do so in a way to not have to continue to pay royalties to CMCC. Though its attempts to maintain patent protection without paying the accompanying royalties were unsuccessful,[92] Celgene was able to leverage the unenforceable and invalid '745 Patent, as well as the additional invalid dosage patents, in its sham litigation with Lannett, as discussed below.

ii. Celgene Filed Sham Litigations to Prevent or Delay Generic Entry.

334. In 2008, Celgene filed a patent infringement lawsuit against Barr, and in 2015 against Lannett, for their thalidomide ANDAs.

335. In 2010, Celgene filed a patent lawsuit against Natco for its lenalidomide ANDA. In 2016, Celgene filed a patent lawsuit against Dr. Reddy's for its lenalidomide ANDA. In 2017,

[91] *Children's Med. Center Corp. v. Celgene Corp.*, No. 13-11573, 2016 WL 3561603 (D. Mass. Feb. 23, 2016).

[92] *Children's Med. Center Corp. v. Celgene Corp.*, No. 13-11573, 2016 WL 5746358 (D. Mass. Sept. 30, 2016).

Celgene filed patent lawsuits against Zydus Pharmaceuticals ("Zydus") and against Cipla Ltd. ("Cipla") for their lenalidomide ANDAs. In 2018, Celgene filed patent lawsuits against Lotus Pharmaceuticals ("Lotus"), Sun Pharmaceutical ("Sun"), Hetero Labs Ltd. ("Hetero"), and Apotex Inc. ("Apotex") for their lenalidomide ANDAs.

336. In all cases, Celgene complained that the generic versions of Thalomid and Revlimid infringed Celgene's patents related to its REMS procedures of ensuring safe use of the drug. Barr, Natco, Lannett, and Dr. Reddy's each counterclaimed, alleging that Celgene's patents are invalid as prior art or for obviousness, under 35 U.S.C. §§ 102 and/or 103. Because Celgene knew that its patents were invalid, it also must have known that the litigation to enforce the invalid patents would be unsuccessful. It brought the actions only because the filing would delay generic entry into the markets.

1. Celgene's Sham Litigation and Citizen Petition Against Barr

337. Barr filed an ANDA with the FDA for a generic version of Thalomid in September 2006. In its application, Barr alleged that Celgene's patents were invalid.

338. As a result, Celgene filed a lawsuit against Barr in 2007,[93] and a citizen petition on September 20, 2007, one (1) year after Barr filed its ANDA with the FDA. The lawsuit was filed solely to take advantage of the 30-month statutory stay of FDA approval for Barr's generic thalidomide product. The patents at issue concerned the method-of-use rather than the pharmaceutical process; the patents were the result of academic conferences, and thus prone to invalidity on the grounds of obviousness. The litigation was a means to collusively and illegally ensure Celgene's continued monopoly.

339. In the lawsuit, Barr counterclaimed, alleging monopolization, conspiracy to monopolize, and anticompetitive acts, including sham litigation.

[93] *Celgene Corp. v. Barr Laboratories, Inc., et al.,* No. 2:07-cv-286 (D.N.J. Jan. 18, 2007) (J. Wigenton).

340. Upon information and belief, while that action was pending, Barr predicted that its generic version of Thalomid, thalidomide capsules in 50mg, 100mg, 150mg, and 200mg, would launch on the market on June 8, 2009. At the same time, it predicted filing an ANDA for its generic version of Revlimid, lenalidomide capsules, on December 27, 2009, and launching that product August 27, 2012.

341. In addition to filing sham litigation against Barr, on September 20, 2007, Celgene also filed a baseless citizen petition with the FDA urging it not to approve Barr's thalidomide ANDA. At a meeting with Celgene in 2012, FDA's Jane Axelrad, Associate Director for Policy at CDER, commented "since 2007, Celgene's citizen's petition states there are safety concerns and this is because the company does not want generics on the market."[94] In its citizen petition, Celgene requested that the FDA withhold approval of any generic thalidomide product, or alternatively: i) require the application for generic thalidomide to be subject to the same conditions of approval applied to Thalomid under Subpart H of 21 C.F.R. Part 314; and ii) prohibit the restricted distribution program for the generic thalidomide product from authorizing prescriptions for, and registering patients with, multiple myeloma, in violation of Celgene's orphan drug exclusivity, which would expire in 2013.

342. Celgene's petition was meritless. It lacked any reasonable regulatory, scientific, medical, or other basis. The FDA lacked statutory authority to withhold approval of generic thalidomide on the bases given by Celgene or to require the actions Celgene requested. Like its litigation against Barr, this citizens petition was also a sham designed to maintain Celgene's monopoly.

[94] Exhibit to MSJ Opp., Dkt. No. 285-15 at PageIDs 16975-6.

343. On December 19, 2008, Barr responded to the petition, arguing that it "is nothing more than yet another attempt by a brand company to block all generic competition using market exclusivity protecting just a single approved indication."[95] Barr explained that Celgene's pretextual safety concerns were "hyperbole designed to improperly play on the public's fears regarding thalidomide," and that Barr's proposed thalidomide would be safe and its label would contain all precautionary information contained in the Thalomid label. Specifically, Barr argued that the law permits it to carve-out from its label Thalomid's protected MM indication, and that "Barr's Thalidomide Labeling Need Not Contain The Multiple Myeloma Indication To Ensure The Safe And Effective Use Of The ANDA Product."

344. Nearly six (6) years later on September 30, 2014, FDA denied Celgene's citizen petition. Specifically, FDA "den[ies] your request that FDA decline to approve any ANDA for thalidomide."

345. Celgene's filing of baseless citizen petitions was part of, an advanced, its scheme to unlawfully monopolize the markets for the subject drugs.

346. Celgene's patent lawsuit against Barr initiated a 30-month stay of FDA approval for Barr's thalidomide ANDA pursuant to 21 U.S.C. § 355 (j)(5)(B)(iii).

347. The parties engaged in discovery through spring 2010. On May 5, 2010, as part of a settlement agreement, the terms of which are confidential, Barr/Teva[96] requested the FDA withdraw Barr's thalidomide ANDA. Barr/Teva withdrew its ANDA due to "lack of commercial viability" while maintaining that "we still believe Teva or another generic drugmaker may file a paragraph IV filing for Revlimid at some point despite the potential difficulties challenging a

[95] Exhibit to MSJ Opp., Dkt. No. 285-17 at PageID 17432.

[96] Teva Purchased Barr in 2008.

controlled-distribution program."[97] On May 26, 2010, the Court approved Barr and Celgene's stipulation of dismissal. This settlement had the anticompetitive effect of keeping Barr's generic thalidomide and generic lenalidomide off the market.

348. The settlement's terms may have included a reverse payment agreement from Celgene to Barr. A reverse payment patent settlement exists when a patent holder, here Celgene, settles a patent infringement action that the patent holder brought by making a payment to a potential competitor in consideration for their agreement to either delay or refrain from entering the patent holder's market.

349. This type of illegal and anticompetitive settlement artificially blocks competition, allowing Celgene to continue charging higher prices. When a patent holder can control an entire market through sham litigation, they can set supracompetitive prices for necessary products, leaving consumers with no choice but to pay the artificially inflated prices.

350. A reverse payment not only allows a patent holder to stranglehold a market, but it also indicates the invalidity of the brand manufacturer's -- Celgene's -- patents. Celgene's patents at issue concern method-of-use for Thalomid and Revlimid, rather than the pharmaceutical process itself. Moreover, Celgene's patents were largely based on academic and government studies and conferences and are thus prone to invalidity on the grounds of obviousness. Celgene's patent litigation was not in good faith.

351. But for the confidential settlement which may have contained illegal pay-for-delay provisions, Barr would have pursued its 2008 thalidomide ANDA, filed a generic lenalidomide ANDA, and launched both of those products in 2009 and 2012, respectively. Celgene's conduct therefore had the anticompetitive effect of delaying and indefinitely postponing the testing and

[97] Exhibit to MSJ Opp., Dkt. No. 285-17 at PageID 17474.

introduction of generic alternatives. This has caused great expense to Plaintiffs Assignors, as a generic lenalidomide product has still never been brought to market.

2. Celgene's Sham Litigation Against Lannett

352. After Celgene and Lannett reached a confidential settlement in 2011, in late 2013 Lannett announced that its BE studies were going well, and it expected to submit a thalidomide ANDA application to the FDA in January 2014. In December 2014, Lannett filed ANDA No. 206601 with the FDA to gain approval to market its generic version of Thalomid. Lannett also filed a Paragraph IV certification, alleging that Celgene's patents were invalid.

353. Celgene filed a patent lawsuit against Lannett in response on January 30, 2015 alleging infringement of fifteen (15) different patents.[98] Lannett filed counterclaims against Celgene, alleging that each and every patent at issue was invalid, was unenforceable, or was not infringed by Lannett's Paragraph IV certification.

354. Celgene's lawsuit triggered a 30-month statutory stay of FDA approval of Lannett's generic thalidomide product.[99]

355. On October 10, 2017, Celgene and Lannett stipulated to a settlement wherein Lannett would change its Paragraph IV certification on the '745 Patent to a Paragraph III certification and no longer seek FDA approval of its ANDA prior to the expiration of the '745 Patent, and Celgene would dismiss its claims of patent infringement.

356. On October 30, 2017, Lannett and Celgene announced that they entered into a settlement and license agreement related to Thalomid that would permit Lannett to manufacture and market its generic thalidomide product as of August 1, 2019. The terms of the license agreement are confidential.

---

[98] *Celgene Corp. v. Lannett Holdings, Inc.*, No. 2:15-cv-00697 (D.N.J. Jan. 30, 2015) (Wigenton, J.).

[99] *See* 21 U.S.C. § 355(j)(5)(B)(iii).

357. The anticompetitive effect of Celgene's conduct was to delay Lannett's initial ANDA filing, and then to further delay FDA approval of Lannett's generic thalidomide product, and finally, to delay the entry date of Lannett's thalidomide product. There are currently no generic thalidomide products available for purchase.

3. Celgene's Sham Litigation Against Natco, Arrow, and Watson

358. Natco Pharma is an Indian generic prescription drug manufacturer that partnered with Arrow and Watson to produce and market a generic version of Revlimid.

359. On or about August 30, 2010, Natco sent Celgene a required notice letter of its Paragraph IV certifications, which contained a detailed factual and legal statement as to why Celgene's Distribution Method Patents, and certain patents that Celgene listed in the Orange Book in connection with NDA No. 21-880 that related to the chemical composition of Revlimid, including, the '517 Patent, 6,281,230 Patent ("'230 Patent"), 6,555,554 Patent ("'554 Patent"), 7,119,106 Patent ("'106 Patent"), and the '800 Patent, among others, are invalid, unenforceable, and /or not infringed by Natco's lenalidomide ANDA.

360. On approximately September 24, 2010, Natco filed ANDA No. 201452 seeking approval for 5 mg, 10 mg, 15mg and 20mg lenalidomide capsules. The ANDA showed that Natco's generic lenalidomide products are bioequivalent to Celgene's Revlimid.

361. Celgene filed a patent infringement suit against Natco on October 8, 2010. In November and December 2012, Celgene caused additional patents related to the chemical composition of Revlimid, patent number 8,288,415 ("'415 Patent") and the '886 Patent, respectively, to be listed in the Orange Book in connection with Revlimid.

362. On November 18, 2010, Natco filed its Answer and counterclaimed that its ANDA does not infringe Celgene's relevant patents, and that Celgene's relevant patents are invalid and unenforceable.

363. On March 14, 2013, Natco sent Celgene another required notice letter of its Paragraph IV certifications, which contained a detailed factual and legal statement explaining that the '415 and '886 patents are invalid, unenforceable, and/or not infringed by Natco's lenalidomide generics.

364. On April 10, 2013, Celgene caused the 8,404,717 ("'717 Patent") to be listed in the Orange Book in connection with Revlimid. On April 30, 2013, the USPTO issued patent 8,431,598 ("'598 Patent") to Celgene.

365. On May 6, 2013, Celgene filed its Fifth Amended Complaint against Natco Pharma, Arrow and Watson, claiming that Natco's lenalidomide generics would infringe the Distribution Method Patents, the '886 Patent, and the '517, '230, '554, '106, '800, '415, '717, and '598 patents. The invalidity of these patents is discussed above.

366. Natco argued that the '517, '230, '554, '106, '800, '415, '717, and '589 patents are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, 112 and/or doctrines of double patenting. Moreover, Natco argued that its lenalidomide generics do not infringe Celgene's '800 Patent as Natco's lenalidomide does not contain lenalidomide hemihydrate.

367. Celgene argued, and the Court agreed, that "hemihydrate" means "a hydrate containing approximately half a mole of water to one mole of the compound forming the hydrate."

368. Accordingly, using this definition, Celgene's '800 Patent is invalid under 35 U.S.C. § 112 for indefiniteness and lack of written description and lack of enablement.

369. Natco filed counterclaims against Celgene, alleging fraud on the USPTO, and invalid and/or unenforceable patents. Celgene's sole purpose in litigating the alleged infringement was to delay generic entry into the Revlimid market.

370. On December 22, 2015, Celgene announced that it reached a settlement with Natco. On January 4, 2016, the District Court issued a consent judgment dismissing all claims with

prejudice. Under the terms of the settlement agreement, Natco Pharma, Arrow, and Watson are enjoined from marketing unlimited quantities of generic lenalidomide until January 1, 2026, one year before the expiration of the at issue patents. Starting in March 2022, Natco will be allowed to market a limited amount of generic lenalidomide. The allowed quantity will increase each year until 2026. "The volume limit is expected to be a mid-single-digit percentage of the total lenalidomide capsules dispensed in the United States during the first full year of entry. The volume limitation is expected to increase gradually each 12 months until March of 2025 and is not expected to exceed one-third of the total lenalidomide capsules dispensed in the U.S. in the final year of the volume-limited license."

371. The anticompetitive effects of Celgene's conduct were to delay Natco's ANDA and generic entry in the Revlimid market. Though Natco filed its lenalidomide ANDA in September 2010, it cannot bring its generic to market until 2022 at limited volumes. Consequently, a generic lenalidomide product continues to be unavailable and Plaintiffs' Assignors are forced to purchase brand-name Revlimid at Celgene's supracompetitive prices until at least 2022, and given volume limitations, likely until 2026. This agreement functions as a "no authorized generic" provision because it restricts Celgene's ability to launch its own generic by providing for penalties in the event an authorized generic product is launched. Additionally, the volume caps described protect the vast majority of Celgene's Revlimid prescription base from generic competition. The net result of the volume restriction and agreement to not launch an authorized generic is that Celgene retains its monopoly for brand Revlimid.

4. Celgene's Sham Litigation Against Dr. Reddy's

372. As part of its unlawful anticompetitive strategy, Celgene filed three patent infringement suits against Dr. Reddy's. It brought the actions only because the filing would delay generic entry into the lenalidomide market.

i. Polymorphic Forms and Methods of Treatment Patents

373. On October 20, 2016, Celgene filed yet another patent infringement action, this time against Dr. Reddy's, for filing its ANDA No. 209348 for various dosages of its generic alternative to Revlimid, allegedly infringing Celgene's '800 Patent, 7,855,217 patent ("'217 Patent"), 7,968,569 patent ("'569 Patent"), 8,530,498 patent ("'498 Patent"), 8,648,095 patent ("'095 Patent"), 9,101,621 patent ("'621 Patent"), and the 9,101,622 patent ("'622 Patent").[100]

374. In its answer, filed on November 18, 2016, Dr. Reddy's claimed that all seven (7) patents asserted were not duly and/or lawfully issued. It also counterclaimed that all seven (7) patents were invalid and/or unenforceable. The parties filed opening Markman briefs on December 19, 2017. On March 23, 2018, Celgene notified the court that the parties resolved their claim construction disputes and would not be filing responsive Markman briefs.

375. A settlement conference was held on January 10, 2019. Expert discovery was set to close on March 13, 2020.

376. On September 17, 2020, the Court entered a consent judgment by whereby Dr. Reddy's agreed to refrain from making, having made, using, selling, offering to sell, importing, or distributing Dr. Reddy's generic version of Revlimid in or for the United States of America, including its territories, possessions, and the Commonwealth of Puerto Rico until the expiration of Celgene's '800 Patent, '217 Patent, '569 Patent, '498 Patent, '095 Patent, '621 Patent, and '622 Patent.[101]

377. The confidential settlement agreement, resolving all three patent litigations between Dr. Reddy's and Celgene, likely amounts to another unlawful "pay-for-delay" agreement

[100] *Celgene Corp. v. Dr. Reddy's Laboratories, Inc.*, No. 2:16-cv-07704 (D.N.J.).

[101] Consent Judgment, *Celgene Corp. v. Dr. Reddy's Laboratories, Inc.*, No. 2:16-cv-07704 (D.N.J.), Dkt. No. 175.

similar to Celgene's settlement agreement with Natco. In exchange for settling the litigations, Celgene had agreed provide Dr. Reddy's "with a license to Celgene's patents required to manufacture and sell certain volume-limited amounts of generic lenalidomide in the United States beginning sometime after the March 2022 volume-limited license date that Celgene previously provided to Natco."[102] Dr. Reddy's would then obtain a license to market unlimited quantities of generic lenalidomide "no earlier than January 31, 2016,"[103] one year before the expiration of the at issue patents. Celgene is likely restricted from launching its own generic through penalties in the event an authorized generic product is launched.[104] The volume caps described protect the vast majority of Celgene's Revlimid prescription base from generic competition and give Dr. Reddy's little to no incentive to lower its price because it cannot gain additional market share.[105] The new result of the pay-for-delay agreement and the likely agreement not to launch an authorized generic is that Celgene retains its monopoly for the brand Revlimid. The anticompetitive effects of Celgene's conduct are to again delay and prevent generic entry into the lenalidomide market. The anticompetitive effects of Celgene's conduct were to delay Dr. Reddy's ANDA and generic entry into the Revlimid market. Though Dr. Reddy's filed its lenalidomide ANDA in 2016, it cannot bring its generic to market until 2022 at limited volumes. Consequently, a generic lenalidomide product continues to be unavailable and Plaintiffs' Assignors are forced to purchase brand-name

[102] https://www.businesswire.com/news/home/20200917005211/en/Bristol-Myers-Squibb-Announces-Settlement-of-U.S.-Patent-Litigation-for-REVLIMID%C2%AE-lenalidomide-With-Dr.-Reddy%E2%80%99s.

[103] *Id*.

[104] Letter, *In re Thalomid and Revlimid Antitrust Litigation*, No. 2:14-cv-06997, Dkt. No. 288, at 7, n.11 (D.N.J. May 21, 2019).

[105] https://www.npr.org/sections/health-shots/2018/05/17/571986468/how-a-drugmaker-gamed-the-system-to-keep-generic-competition-away.

Revlimid at Celgene's supracompetitive prices until at least 2022, and given volume limitations, likely until 2026.

ii. Additional Methods of Treatment Patents

378. On July 20, 2017, Celgene filed suit against Dr. Reddy's for filing ANDA No. 209348 for various dosages of its generic alternative to Revlimid, allegedly also infringing Celgene's '740 Patent, '717 Patent, and '120 Patent.[106]

379. Dr. Reddy's filed its answer on October 3, 2017, and an amended answer on October 18, 2017. Celgene filed its Answer to Dr. Reddy's counterclaim on November 15, 2017.

380. A settlement conference was held on January 10, 2019. Expert discovery was set to close on March 26, 2020.

381. On March 2, 2020, the court ordered the parties to engage in confidential mediation, which was held on April 2, 2020.

382. On September 17, 2020, the Court entered a consent judgment by whereby Dr. Reddy's agreed to refrain from making, having made, using, selling, offering to sell, importing, or distributing Dr. Reddy's generic version of Revlimid in or for the United States of America, including its territories, possessions, and the Commonwealth of Puerto Rico until the expiration of Celgene's '740 Patent, '717 Patent, and '120 Patent.[107] As described above, this consent judgment was pursuant to a settlement agreement that likely contained anticompetitive provisions amounting to a "pay-for-delay" agreement.

383. The anticompetitive effects of Celgene's conduct are to again delay and prevent generic entry into the lenalidomide market.

---

[106] *Celgene Corp. v. Dr. Reddy's Laboratories, Inc.*, No. 2:17-cv-05314 (D.N.J.).

[107] Consent Judgment, *Celgene Corp. v. Dr. Reddy's Laboratories, Inc.*, No. 2:17-cv-05314 (D.N.J.), Dkt. No. 120.

iii. Methods of Delivery Patents

384. On April 12, 2018, Celgene filed suit against Dr. Reddy's for filing ANDA No. 209348 for various dosages of its generic alternative to Revlimid, allegedly also infringing Celgene's '720 Patent, '977 Patent, '784 Patent, '886 Patent, and '531 Patent.[108]

385. Dr. Reddy's filed its answer and counterclaims on April 30, 2018, and an amended answer with counterclaims on May 31, 2018. Celgene filed its answer to Dr. Reddy's counterclaims on June 28, 2018.

386. On February 14, 2019, the parties agreed to stay the action until July 1, 2019. On July 1, 2019, the parties again agreed to stay the action through January 9, 2020, subject to renewal by the parties. On March 4, 2020, the parties again agreed to stay the action until June 15, 2020.

387. On September 17, 2020, the Court entered a consent judgment by whereby Dr. Reddy's agreed to refrain from making, having made, using, selling, offering to sell, importing, or distributing Dr. Reddy's generic version of Revlimid in or for the United States of America, including its territories, possessions, and the Commonwealth of Puerto Rico until the expiration of Celgene's '720 Patent, '977 Patent, '784 Patent, '886 Patent, and '531 Patent.[109] As described above, this consent judgment was pursuant to a settlement agreement that likely contained anticompetitive provisions amounting to a "pay-for-delay" agreement.

388. The anticompetitive effects of Celgene's conduct are to again delay and prevent generic entry into the lenalidomide market.

5. Celgene's Sham Litigation Against Zydus

[108] *Celgene Corp. v. Dr. Reddy's Laboratories, Inc.*, No. 2:18-cv-06378 (D.N.J.).

[109] Consent Judgment, *Celgene Corp. v. Dr. Reddy's Laboratories, Inc.*, No. 2:18-cv-06378 (D.N.J.), Dkt. No. 67.

389. As part of its unlawful anticompetitive strategy, Celgene filed two patent infringement suits against Zydus. It brought the actions only because the filings would delay generic entry into the lenalidomide market.

i. Polymorphic Form and Methods of Treatment Patents

390. On April 12, 2017, Celgene filed a patent infringement action against Zydus and its healthcare arm, Cadila Healthcare Limited, for filing ANDA No. 210154 for various dosages of its generic alternative to Revlimid, allegedly infringing Celgene's same '800 Patent, '217 Patent, '569 Patent, '498 Patent, '095 Patent, '621 Patent, and '622 Patent.[110] This combination of patents has become central to Celgene's strategy of blocking generic competitors.

391. On August 7, 2017, Zydus filed its answer and counterclaimed that each of Celgene's asserted patents are invalid, unenforceable, or noninfringed.

392. On January 14, 2019, the Court ordered mediation between the parties.

393. On May 10, 2019, the Court issues an Amended Scheduling Order. On December 30, 2019, the court ordered the parties to present a final schedule for the remainder of expert discovery that took into account the age of the case.

394. On March 13, 2020, Celgene filed a motion, under seal, to stay the proceedings.

395. On March 24, 2021, the Court entered a consent judgment by whereby Zydus agreed to refrain from making, having made, using, selling, offering to sell, importing, or distributing Zydus's generic version of Revlimid in or for the United States of America, including its territories, possessions, and the Commonwealth of Puerto Rico until the expiration of Celgene's '800 Patent,'569 Patent, '357 Patent, '219 Patent, '598 Patent,'498 Patent, '095 Patent, '621

[110] *Celgene Corp. v. Zydus Pharmaceuticals (USA) Inc. et al.*, No. 2:17-cv-02528 (D.N.J.).

Patent, and '622 Patent.[111] This consent judgment was pursuant to a settlement agreement that likely contained anticompetitive provisions amounting to a "pay-for-delay" agreement.

396. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation, are to delay and prevent generic entry into the lenalidomide market.

ii. Additional Polymorphic Form Patents

397. On April 27, 2018, Celgene filed yet another patent infringement action against Zydus for filing ANDA No. 210154 for various dosages of its generic alternative to Revlimid, allegedly also infringing Celgene's 7,977,357 patent ("'357 Patent"), 8,193,219 patent ("'219 Patent"), and '598 Patent.[112]

398. On July 9, 2018, Zydus filed its answer.

399. On January 14, 2019, the court ordered mediation between the parties. Fact discovery closed on August 30, 2019.

400. On March 13, 2020, Celgene filed a motion, under seal, to stay the proceedings.

401. On March 24, 2021, the Court entered a consent judgment by whereby Zydus agreed to refrain from making, having made, using, selling, offering to sell, importing, or distributing Zydus's generic version of Revlimid in or for the United States of America, including its territories, possessions, and the Commonwealth of Puerto Rico until the expiration of Celgene's '800 Patent,'569 Patent, '357 Patent, '219 Patent, '598 Patent,'498 Patent, '095 Patent, '621 Patent, and '622 Patent.[113] This consent judgment was pursuant to a settlement agreement that likely contained anticompetitive provisions amounting to a "pay-for-delay" agreement.

---

[111] Consent Judgment, *Celgene Corp. v. Zydus Pharm*, No. 2:17-cv-2528 (D.N.J.), Dkt. No. 210.

[112] *Celgene Corp. v. Zydus Pharmaceuticals (USA) Inc., et al.*, No. 2:18-cv-08519 (D.N.J.).

[113] Consent Judgment, *Celgene Corp. v. Zydus Pharm*, No. 2:18-cv-8519 (D.N.J.), ECF No. 119.

402. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation, are to delay and prevent generic entry into the lenalidomide market.

6. Celgene's Sham Litigation Against Cipla

403. As part of its unlawful anticompetitive strategy, Celgene filed three patent infringement suits against Cipla. It brought the actions only because the filings would delay generic entry into the lenalidomide market.

i. Polymorphic Form and Methods of Treatment Patents

404. On August 15, 2017, Celgene filed a patent infringement action, this time against Cipla, for filing its ANDA No. 210435 for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe the same combination of the '800 Patent, '217 Patent, '569 Patent, '498 Patent, '095 Patent, '621 Patent, and '622 Patent.[114]

405. On August 16, 2018, Celgene stipulated to a dismissal of its claims regarding the '217 Patent and filed a covenant not to sue Cipla for infringement of the '217 Patent.

406. On January 14, 2019, the Court ordered mediation between the parties. On February 6, 2019, the parties informed the court that Markman hearings were no longer necessary.

407. On June 4, 2019, the court entered an amended scheduling order. On June 8, 2020, the docket was administratively terminated, with the filings of the docket remaining in force and incorporated by reference into Civil Action No. 19-14731, discussed below.

408. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation, are to delay and prevent generic entry into the lenalidomide market.

ii. Additional Polymorphic Form Patents

409. On May 8, 2018, Celgene filed a patent infringement action against Cipla for filing its ANDA No. 210435 for various dosages of its generic alternative to Revlimid, which Celgene

[114] *Celgene Corp. v. Cipla Ltd.*, No. 2:17-cv-06163 (D.N.J.).

alleged would also infringe the same combination of the '357 Patent, '219 Patent, and '598 Patent.[115]

410. On July 16, 2018, Cipla filed its answer and counterclaims. On August 20, 2018, Celgene filed its answer to Cipla's counterclaim.

411. On April 30, 2019, the court issued a stipulated order in which the parties agreed not to contest a finding that products derived from Cipla's ANDA would infringe Celgene's patents at issue. On June 8, 2020, the docket was administratively terminated, with the filings of the docket remaining in force and incorporated by reference into Civil Action No. 19-14731, discussed below.

412. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation, are to delay and prevent generic entry into the lenalidomide market.

iii. Additional Litigation

413. On July 3, 2019, Celgene filed another patent infringement action against Cipla for filing its ANDA No. 213165 for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe the '800 Patent, '217 Patent, '569 Patent, '498 Patent, '095 Patent, '621 Patent, '622 Patent, '740 Patent, '717 Patent, and '120 Patent.[116]

414. On August 26, 2019, Cipla filed its answer and counterclaims, alleging that the patents at issue were all invalid, unenforceable, or would not be infringed by activity described in Cipla's Paragraph IV Certification for ANDA No. 213165. On October 18, 2019, Celgene filed its answer to Cipla's counterclaim.

[115] *Celgene Corp. v. Cipla Ltd.*, No. 2:18-cv-08964 (D.N.J.).

[116] *Celgene Corp. v. Cipla Ltd.*, No. 2:19-cv-14731 (D.N.J.).

415. On May 28, 2020, Celgene filed its First Amended Complaint, alleging that Cipla's ANDA would infringe every patent at issue in the prior two suits filed against Cipla.[117] On July 23, 2020, Celgene filed its answer to Cipla's counterclaims.

416. On December 14, 2020, Celgene and Cipla stipulated and consented to the entry of judgment and an injunction prohibiting Cipla from marketing its generic lenalidomide until the expiration of the patents-in-suit listed above pursuant to a settlement agreement.

417. The confidential settlement agreement, resolving all patent litigations between Cipla and Celgene, likely amounts to another unlawful "pay-for-delay" agreement similar to Celgene's settlement agreement with Natco, Dr. Reddy's, and, as below, Alvogen. In exchange for settling the litigations, Celgene has agreed to provide Cipla "with a license to Celgene's patents required to manufacture and sell certain volume-limited amounts of generic lenalidomide in the United States beginning on a confidential date that is some time after March 2022."[118] Cipla would then obtain a license to market volume-limited quantities of generic lenalidomide until January 31, 2026, one year before the expiration of the at issue patents.[119] While the exact percentages are confidential, Celgene has reserved for itself the vast majority of the market. Given the public terms available, which mostly mirror those struck with other would-be generic Revlimid and Thalomid manufacturers, Celgene is also likely restricted from launching its own generic through penalties in the event an authorized generic product is launched.[120] The volume caps described protect the vast majority of Celgene's Revlimid prescription base from generic competition and give Cipla

[117] First Amended Complaint, *Celgene Corp. v. Cipla Ltd.*, No 2:19-cv-14731, ECF No. 64.

[118] https://www.businesswire.com/news/home/20201211005052/en/Bristol-Myers-Squibb-Announces-Settlement-of-U.S.-Patent-Litigation-for-REVLIMID%C2%AE-lenalidomide-with-Cipla.

[119] *Id.*

[120] Letter, *In re Thalomid and Revlimid Antitrust Litigation*, No. 2:14-cv-06997, Dkt. No. 288, at 7, n.11 (D.N.J. May 21, 2019).

little to no incentive to lower its prices because it cannot gain additional market share.[121] As such, financial analysts concluded that the settlement was a "positive surprise," advising that "price erosion will remain much lower than in a multiplayer generic market," with the anticipated "staggered" entry of volume-limited generics likely to significantly defray natural price erosion until the volume limits expire in 2026."[122] Credit Suisse analysts estimate the settlement agreement delivers Cipla $300 million at net present value.[123] The net result of the pay-for-delay agreement and the likely agreement not to launch an authorized generic is that Celgene retains its monopoly for brand Revlimid. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation and inducing another confidential settlement agreement with a generic competitor that may include illegal pay-for-delay provisions, are to delay and prevent generic entry into the lenalidomide market.

7. Celgene's Sham Litigation Against Alvogen and Lotus

418. As part of its unlawful anticompetitive strategy, Celgene filed two patent infringement suits against Lotus and Alvogen, Inc. ("Alvogen"). It brought the actions only because the filings would delay generic entry into the lenalidomide market.

i. Polymorphic Form, Distribution Method, and Methods of Treatment Patents

419. On September 6, 2017, Celgene filed a patent infringement action against Lotus and Alvogen for filing ANDA No. 210480 for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe its '517 Patent, '720 Patent, '977 Patent, '784

[121] https://www.npr.org/sections/health-shots/2018/05/17/571986468/how-a-drugmaker-gamed-the-system-to-keep-generic-competition-away.

[122] *Id.*

[123] *Id.*

Patent, '740 Patent, '800 Patent, '217 Patent, '569 Patent, '886 Patent, '717 Patent, '498 Patent, '531 Patent, '095 Patent, '120 Patent, '621 Patent, and the '622 Patent.[124]

420. On October 5, 2017, Lotus and Alvogen filed its answer and counterclaims, seeking declaratory judgments that the patents at issue were invalid, unenforceable, or would not be infringed by activity described in Lotus and Alvogen's paragraph IV Certification.

421. On March 29, 2019, Celgene, Lotus, and Alvogen stipulated and consented to an entry of judgment and an injunction prohibiting Lotus and Alvogen from marketing its generic lenalidomide until the expiration of the patents-in-suit listed above pursuant to a settlement agreement.

422. The confidential settlement agreement, resolving both patent litigations between Alvogen and Celgene, likely amounts to another unlawful "pay-for-delay" agreement similar to Celgene's settlement agreement with Natco. In exchange for settling the litigations, Celgene has agreed to provide Alvogen "with a license to Celgene's patents required to manufacture and sell certain volume-limited amounts of generic lenalidomide in the United States beginning on a confidential date that is some time after the March 2022 volume-limited license date that Celgene previously provided to Natco."[125] Alvogen would then obtain a license to market volume-limited quantities of generic lenalidomide until January 31, 2026, one year before the expiration of the at issue patents.[126] While the exact percentages are confidential, Celgene has reserved for itself the vast majority of the market, with Alvogen's allotted volume increasing to only peak at "no more than a single-digit percentage in the final volume-limited period."[127] Celgene is also likely

[124] *Celgene Corp. v. Lotus Pharmaceutical Co., Ltd., et al.*, No. 2:17-cv-06842 (D.N.J.).

[125] https://www.businesswire.com/news/home/20190329005384/en/Celgene-Settles-U.S.-REVLIMID%C2%AE-Patent-Litigation-with-Alvogen.

[126] *Id.*

[127] *Id.*

restricted from launching its own generic through penalties in the event an authorized generic product is launched.[128] The volume caps described protect the vast majority of Celgene's Revlimid prescription base from generic competition and give Alvogen little to no incentive to lower its prices because it cannot gain additional market share.[129] The net result of the pay-for-delay agreement and the likely agreement not to launch an authorized generic is that Celgene retains its monopoly for the brand Revlimid.

423. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation and inducing another confidential settlement agreement with a generic competitor that may include illegal pay-for-delay provisions, are to delay and prevent generic entry into the lenalidomide market.

ii. Additional Polymorphic Form Patents

424. On July 10, 2018, Celgene filed a patent infringement action against Lotus and Alvogen for filing ANDA No. 210480 for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe its '357 Patent, '219 Patent, and the '598 Patent.[130] The patents that Celgene has claimed would be infringed in this case, however, have not been submitted to the Orange Book by Celgene in association with Revlimid as required pursuant to 21 U.S.C. §355(b)(1) and attendant FDA regulations. Celgene was required to list with its NDA, or within thirty days for a new patent after the NDA has been submitted, any patents for which an infringement claim could reasonably be asserted against an unlicensed entity attempting to manufacture, use or sell its drug. By citing these patents that were not filed in the Orange Book,

---

[128] Letter, *In re Thalomid and Revlimid Antitrust Litigation*, No. 2:14-cv-06997, ECF No. 288, at 7, n.11 (D.N.J. May 21, 2019).

[129] https://www.npr.org/sections/health-shots/2018/05/17/571986468/how-a-drugmaker-gamed-the-system-to-keep-generic-competition-away.

[130] *Celgene Corp. v. Lotus Pharmaceutical Co., Ltd., et al*, No. 2:18-cv-11518 (D.N.J.).

Celgene is either filing a frivolous infringement claim for a patent that it does not believe could be reasonably asserted or failing to list patents properly which could give rise to administrative action or potentially additional antitrust liability if done in an attempt to delay filing and further extend its monopoly.

425. In their notice letter to Celgene, Lotus and Alvogen also alleged that the '517 Patent, '720 Patent, '977 Patent, '784 Patent, '740 Patent, '800 Patent, '217 Patent, '569 Patent, '886 Patent, '717 Patent, '498 Patent, '531 Patent, '095 Patent, '120 Patent, '621 Patent, and the '622 Patent were all invalid, unenforceable, or would not be infringed by activity described in Lotus and Alvogen's Paragraph IV Certification.

426. On March 29, 2019, Celgene, Lotus, and Alvogen stipulated and consented to an entry of judgment and an injunction prohibiting Lotus and Alvogen from marketing and selling its generic lenalidomide until the expiration of the patents-in-suit listed above. As described above, this consent judgment was pursuant to a settlement agreement that likely contained anticompetitive provisions amounting to a pay-for-delay" agreement.

427. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation and inducing another confidential settlement agreement with a generic competitor that may include illegal pay-for-delay provisions, are to delay and prevent generic entry into the lenalidomide market.

8. Celgene's Sham Litigation Against Sun

428. In Spring 2018, Sun filed its ANDA No. 211846 for generic lenalidomide. On May 30, 2018, Sun sent written notice of its Paragraph IV Certification to Celgene alleging that the patents-in-suit are invalid and/or will not be infringed by Sun's ANDA.

429. On July 13, 2018, Celgene filed yet another patent infringement action against a generic manufacturer, this time against Sun Pharmaceuticals Industries, Inc. and related entities

for filing its ANDA for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe its '800 Patent, '217 Patent, and their '569 Patent.[131]

430. On August 14, 2018, Sun filed its answer and counterclaim, alleging that Celgene's asserted patents are invalid, unenforceable, or uninfringed.

431. On November 21, 2019, the court issued an amended scheduling order. On December 12, 2019, the court canceled Markman hearings upon the parties' joint motion.

432. On June 22, 2021, the Court entered a consent judgment by whereby Sun agreed to refrain from making, having made, using, selling, offering to sell, importing, or distributing Sun's generic version of Revlimid in or for the United States of America, including its territories, possessions, and the Commonwealth of Puerto Rico until the expiration of Celgene's '800 Patent, '217 Patent, '569 Patent, '357 Patent, '219 Patent, '598 Patent,'498 Patent, '095 Patent, '621 Patent, and '622 Patent.[132]

433. The confidential settlement agreement, resolving all three patent litigations between Sun and Celgene, likely amounts to another unlawful "pay-for-delay" agreement similar to Celgene's settlement agreement with Natco. In exchange for settling the litigations, Celgene had agreed provide Sun "with a license to Celgene's patents required to manufacture and sell certain limited quantity of generic lenalidomide capsules in the US beginning on a confidential date that is sometime after March 2022."[133] Sun would then obtain a license to market unlimited quantities of generic lenalidomide capsules beginning January 31, 2016,[134] one year before the

[131] *Celgene Corp. v. Sun Pharm. Indus., Inc., et al.*, No. 2:18-cv-11630 (D.N.J.).

[132] Consent Judgment, *Celgene Corp. v. Sun Pharm. Indus., Inc., et al.*, No. 2:18-cv-11630 (D.N.J.), Dkt. No. 119.

[133] https://sunpharma.com/wp-content/uploads/2021/06/Press-Release-Settlement-of-Patent-Litigation-for-Generic-Revlimid-in-US.pdf.

[134] *Id.*

expiration of the at issue patents. Celgene is likely restricted from launching its own generic through penalties in the event an authorized generic product is launched.[135] The volume caps described protect the vast majority of Celgene's Revlimid prescription base from generic competition and give Sun little to no incentive to lower its price because it cannot gain additional market share.[136] The new result of the pay-for-delay agreement and the likely agreement not to launch an authorized generic is that Celgene retains its monopoly for the brand Revlimid. The anticompetitive effects of Celgene's conduct are to again delay and prevent generic entry into the lenalidomide market. The anticompetitive effects of Celgene's conduct were to delay Sun's ANDA and generic entry into the Revlimid market. Though Sun filed its lenalidomide ANDA in 2018, it cannot bring its generic to market until 2022 at limited volumes. Consequently, a generic lenalidomide product continues to be unavailable and Plaintiffs' Assignors are forced to purchase brand-name Revlimid at Celgene's supracompetitive prices until at least 2022, and given volume limitations, likely until 2026.

9. Celgene's Sham Litigation Against Hetero

434. As part of its unlawful anticompetitive strategy, Celgene filed three patent infringement suits against Hetero. It brought the actions only because the filings would delay generic entry into the lenalidomide market.

i. Polymorphic Forms and Methods of Treatment Patents

435. In the Fall 2018, Hetero filed its ANDA for generic lenalidomide. On November 9, 2018, Hetero sent written notice of its Paragraph IV Certification to Celgene alleging that the patents-in-suit are invalid and/or will not be infringed by Hetero's ANDA.

---

[135] Letter, *In re Thalomid and Revlimid Antitrust Litigation*, No. 2:14-cv-06997, Dkt. No. 288, at 7, n.11 (D.N.J. May 21, 2019).

[136] https://www.npr.org/sections/health-shots/2018/05/17/571986468/how-a-drugmaker-gamed-the-system-to-keep-generic-competition-away.

436. On December 20, 2018, Celgene filed yet another patent infringement action against a generic manufacturer, this time against Hetero Labs, Ltd,[137] for filing ANDA No. 212414 for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe its '800 Patent, '217 Patent, '363 Patent, and '929 Patent.[138]

437. On March 11, 2019, Hetero filed its answer and counterclaim, alleging that Celgene's asserted patents are invalid, unenforceable, or uninfringed. On April 15, 2019, Celgene filed its answer to Hetero's counterclaim.

438. On January 21, 2020, the court entered a stipulation dismissing without prejudice Celgene's claims relating to the '217 Patent, '363 Patent, and the '929 Patent. The case went forward only as to the '800 Patent.

439. On January 11, 2021, the docket was administratively terminated, with the filings of the docket remaining in force and incorporated by reference into Civil Action No. 20-14389, discussed below.

440. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation, are to delay and prevent generic entry into the lenalidomide market.

ii. Additional Methods of Treatment Patents

441. On July 16, 2019, Celgene filed yet another patent infringement action against Hetero for filing ANDA No. 212414 for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe its '740 Patent, '569 Patent, '717 Patent, '498 Patent, '095 Patent, '120 Patent, '621 Patent, and '622 Patent.[139]

---

[137] The complaint also named Hetero Labs Limited Unit-V, Hetero Drugs Limited, and Hetero USA, Inc. (collectively, "Hetero").

[138] *Celgene Corp. v. Hetero Labs Ltd., et al.*, No. 2:18-cv-17463 (D.N.J.).

[139] *Celgene Corp. v. Hetero Labs Ltd., et al.*, No. 2:19-cv-15449 (D.N.J.).

442. On October 11, 2019, Hetero filed its answer and counterclaims against Celgene, for which Celgene filed an answer on November 15, 2019.

443. On December 18, 2019, the court issues a pretrial scheduling order.

444. On January 11, 2021, the docket was administratively terminated, with the filings of the docket remaining in force and incorporated by reference into Civil Action No. 20-14389.

445. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation, are to delay and prevent generic entry into the lenalidomide market.

ii. Additional Litigation

446. On October 13, 2020, Celgene filed yet another patent infringement action against Hetero for filing ANDA No. 212414 for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe its '357 Patent and '219 Patent.[140]

447. On November 13, 2020, Hetero filed its answer and counterclaims against Celgene.

448. On January 8, 2021, Celgene filed an amended complaint. On January 26, 2021, Hetero filed its answer to same and counterclaims against Celgene. Celgene filed its answer to counterclaims on February 23, 2021.

449. On September 27, 2021, the Court entered a consent judgment by whereby Hetero agreed to refrain from making, having made, using, selling, offering to sell, importing, or distributing Hetero's generic version of Revlimid in or for the United States of America, including its territories, possessions, and the Commonwealth of Puerto Rico until the expiration of Celgene's '740 Patent, '800 Patent, '569 Patent, '357 Patent, '219 Patent,'717 Patent, '498 Patent, '095 Patent, '120 Patent, '621 Patent, and '622 Patent.[141] This consent judgment was pursuant to a

[140] *Celgene Corp. v. Hetero Labs Ltd., et al.*, No. 2:20-cv-14389 (D.N.J.).

[141] Consent Judgment, *Celgene Corp. v. Hetero Labs,* No. 2:20-cv-14389 (D.N.J.), Dkt. No. 51.

settlement agreement that likely contained anticompetitive provisions amounting to a "pay-for-delay" agreement.

450. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation, are to delay and prevent generic entry into the lenalidomide market.

10. Celgene's Sham Litigation Against Apotex

451. In Winter 2017, Apotex filed its ANDA for generic lenalidomide. On November 28, 2017, Apotex sent written notice of its Paragraph IV Certification to Celgene alleging that the patents-in-issue are invalid and/or will not be infringed by Apotex's ANDA.

452. On January 11, 2018, Celgene filed yet another patent infringement action against a generic manufacturer, this time against Apotex for filing ANDA No. 211022 for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe its '720 Patent, '977 Patent, '784 Patent, '886 Patent, '531 Patent, '800 Patent, '217 Patent, '363 Patent, and '929 Patent.[142]

453. On August 30, 2018, Apotex filed its answer and affirmative defenses, alleging that Celgene's asserted patents are invalid, unenforceable, or uninfringed. Apotex alleged that five of the patents-in-suit are unenforceable due to patent misuse because Celgene asserted the patents even though no reasonable litigant could believe they were valid in light of prior proceedings in front of the PTAB.

454. On April 30, 2019, the court issued a consent judgment that the '217 Patent was not infringed by ANDA No. 211022.

455. On May 8, 2019, the court issued an order bifurcating the claims and staying the action as to the '720 Patent, '977 Patent, '784 Patent, '886 Patent, and the '531 Patent.

[142] *Celgene Corp. v. Apotex Inc.*, No. 2:18-cv-00461 (D.N.J.).

456. The case proceeded as to claims concerning the '800 Patent, '363 Patent, and the '929 Patent.

457. On March 10, 2021, the Court entered a consent judgment by whereby Apotex agreed to refrain from making, having made, using, selling, offering to sell, importing, or distributing Apotex's generic version of Revlimid in or for the United States of America, including its territories, possessions, and the Commonwealth of Puerto Rico until the expiration of Celgene's '740 Patent, '800 Patent, '363 Patent, '357 Patent, '219 Patent,'717 Patent, '598 Patent, '929 Patent, and '120 Patent.[143] This consent judgment was pursuant to a settlement agreement that likely contained anticompetitive provisions amounting to a "pay-for-delay" agreement.

458. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation, are to delay and prevent generic entry into the lenalidomide market.

VII. CELGENE INTENDED TO AND DID HARM COMPETITION.

459. Celgene's scheme was intended to and did in fact block and delay generic thalidomide and lenalidomide entry into the market, disrupted the normal distribution channels, and manipulated the statutory and regulatory mechanisms by which generic competition takes place, and otherwise excluded generic competitors from efficiently marketing and distributing their products.

460. But for Celgene's anticompetitive scheme, generic Thalomid would have been brought to market possibly at least as early as spring of 2009. Celgene illegally prevented competitors, including Mylan in 2004, Barr in 2005, and Lannett and 2007, from obtaining Thalomid samples for bioequivalence testing. When Barr filed its ANDA in September 2005, Celgene executed a contract with Barr's API supplier that contained an anticompetitive exclusive

[143] Consent Judgment, *Celgene Corp. v. Apotex Inc.,* No. 2:18-cv-461 (D.N.J.), Dkt. No. 133.

dealing provision that created deficiencies in Barr's ANDA application and required Barr to undergo new bio-studies and validation testing, delaying Barr's ANDA one year. When Barr filed its ANDA in September 2006, Celgene filed a sham litigation suit to enforce its invalid and unenforceable patents. The litigation was halted when Celgene and Barr reached a confidential settlement which resulted in a continued absence of generic Thalomid from the market.

461. But for Celgene's anticompetitive conduct, generic Revlimid would have entered the market in 2010 or soon thereafter. Celgene once again prevented multiple competitors including Mylan, Natco Pharma, Dr. Reddy's, Teva, and Watson from obtaining Revlimid from Celgene for BE testing. Celgene refused to supply samples to Mylan, and Mylan has been unable to complete BE testing or file an ANDA for lenalidomide. Natco filed its lenalidomide ANDA in September 2010 and would have brought generic Revlimid to market shortly thereafter, but for Celgene's sham patent infringement lawsuit and the subsequent settlement wherein Natco agreed not to sell generic lenalidomide until 2022, and then only in limited quantities. Dr. Reddy's filed its lenalidomide ANDA in 2016, after which Celgene once again filed a sham patent litigation. Lannett filed its thalidomide ANDA in December 2014, after which Celgene filed a sham patent litigation that resulted in a settlement wherein Lannett's thalidomide cannot be sold until August 2019. Zydus, CIPLA, Lotus, Hetero, Apotex and Sun each filed lenalidomide ANDAs and were met with Celgene's serial sham litigation tactic, delaying the entry of their generic Revlimid products into the market.

462. All of Celgene's patents on Revlimid are invalid under 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrines of double-patenting.

463. Celgene's unjustifiable refusal to cooperate with the generic ANDA filers directly prevented generic filers from obtaining FDA approval. But for Celgene's unlawful conduct, the FDA would have given final approval to the pending generic manufacturer's ANDAs and allowed them to enter the market.

464. Celgene cannot justify its scheme by pointing to any consumer benefit. Generic drugs offer enormous cost savings, which outweigh any non-pretextual, if there even are any, justifications Celgene could possibly offer.

VIII. CELGENE'S FORECLOSURE OF GENERIC COMPETITION FOR THALOMID AND REVLIMID CAUSED PLAINTIFFS' ASSIGNORS TO PAY MORE THAN THEY WOULD HAVE PAID IN AN UNMANIPULATED MARKET.

465. Celgene's scheme suppressed the ability of generic Thalomid and Revlimid substitutes to compete in the market under the governing statutory and regulatory scheme.

466. The absence of generic competition injured Plaintiffs' Assignors because they would have paid much less for Thalomid and Revlimid, or their generic alternatives, by substituting purchases of less expensive AB-rated generic drugs for their purchases of more expense branded drugs, receiving discounts on their remaining purchases of branded drugs, and by purchasing generic versions of Thalomid and Revlimid at lower prices sooner.

467. As a result, Plaintiffs' Assignors sustained substantial losses and damages to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

IX. CELGENE'S FORECLOSURE OF GENERIC COMPETITION FOR THALOMID AND REVLIMID AFFECTED INTERSTATE COMMERCE FOR THOSE DRUGS.

468. At all material times, Thalomid and Revlimid, manufactured and sold by Celgene, were shipped across state lines and sold to customers located outside of its state of manufacture.

469. Between at least 2010 and the present, in connection with the purchase and sale of Thalomid and Revlimid, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

470. At all material times, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Celgene as charged were within the flow of, and have substantially affected interstate commerce, money, contracts, bills, and other forms of business communications were transmitted in a continuous and uninterrupted flow across state lines.

X. CELGENE MAINTAINED MONOPOLY POWER OVER THALOMID AND REVLIMID AND THEIR GENERIC FORMS.

471. At all relevant times, Celgene has had power over the market for Thalomid and Revlimid in all their forms and dosages, which are still only available in the form of branded Thalomid and branded Revlimid. Celgene has and continues to have the power to maintain and increase the price of Thalomid and Revlimid to supracompetitive levels without losing sales, because Celgene has successfully conspired to keep AB-rated generic versions of Thalomid and Revlimid from reaching the U.S. market at all.

472. A small, but significant, non-transitory price increase for Revlimid or Thalomid by Celgene would not have caused a significant loss of sales.

473. Celgene needed to control only Thalomid and Revlimid and their AB-rated generic equivalents, and no other products, to maintain the price of Thalomid and Revlimid at supracompetitive prices. Only the market entry of a competing AB-rated generic version of those drugs would render Celgene unable to maintain its market monopoly.

474. If Plaintiffs are legally required to prove market power through circumstantial evidence by first defining a relevant product market, the relevant market for Thalomid is all dosages of thalidomide, *i.e.*, Thalomid and its AB-rated generic equivalents, and for Revlimid is all dosages of lenalidomide, *i.e.*, Revlimid and its AB-rated generic equivalents.

475. Thalomid and Revlimid do not exhibit significant, positive cross-elasticity of demand regarding price with any other product, due to the FDA regulatory hurdles incident to

securing A-B rating and laws allowing pharmacists to substitute only AB-rated generics for prescribed branded drugs.

XI. CELGENE MONOPOLIZED THE RELEVANT MARKET.

476. There are no interchangeable drug products available for purchasers of Thalomid and Revlimid.

477. Celgene needed to control the output of Thalomid and Revlimid and its AB-rated generic equivalents only, and no other products, to maintain the price of Thalomid and Revlimid profitably at supracompetitive prices. Only the market entry of a competing AB-rated generic version of Revlimid or Thalomid would render Celgene unable to profitably maintain its current prices of those drugs without losing substantial sales.

478. Celgene also sold branded Thalomid and Revlimid well over marginal costs, and substantially more than the competitive price, and enjoyed unusually high profit margins.

479. Celgene has had, and so exercised, the power to exclude and restrict competition for Thalomid and Revlimid.

480. Without the power to exclude and restrict competition for Thalomid and Revlimid, and the ability to sell its own branded version of those drugs at prices well over marginal costs, it would not have been economically rational for Celgene to pay Natco, and potentially other generic manufacturers, unusually exorbitant settlement payments to delay the launch of generic Thalomid and Revlimid.

481. At all relevant times, Celgene has enjoyed the benefits of high barriers to entry with respect to competition to the above-defined market due to patent and other regulatory protections.

482. The relevant geographic markets are (i) the United States and its territories, and (ii) each of the states in which Plaintiffs' Assignors' Enrollees purchased Revlimid and/or Thalomid

and under whose laws Plaintiffs assert claims for relief. At all relevant times, Celgene's market share in the relevant market was, and continues to be, 100%.

XII. ANTITRUST INJURY

483. Celgene's use of the regulatory process as an anticompetitive tool to block and delay generic competition for Thalomid and Revlimid keeps costs high for insurers like Plaintiffs' Assignors.

484. Plaintiffs' Assignors paid substantial sums to purchase Thalomid and Revlimid during the relevant times and their members paid additional sums in cost-sharing for Thalomid and Revlimid. Because of Celgene's illegal conduct, Plaintiffs' Assignors have been compelled to pay artificially inflated prices for Thalomid and Revlimid. Those prices have been substantially higher than the prices Plaintiffs' Assignors would have paid for generic Thalomid and generic Revlimid but for the illegal conduct alleged. Plaintiffs' Assignors continue to pay artificially high, supracompetitive prices for Thalomid and Revlimid as a direct result of Celgene's anticompetitive conduct.

485. Consequently, Plaintiffs' Assignors, as purchasers of Thalomid and Revlimid, having paid for Thalomid and Revlimid, have sustained substantial losses and damage to their business and property in the form of overcharges. These losses and damages are continuing and accumulating. The full amount, forms, and components of such damages will be determined after discovery and upon proof at trial.

486. Celgene's efforts to restrain competition in the defined relevant markets has and continues to substantially affect interstate and intrastate commerce throughout the United States.

487. Excluding generic competitors prevented price competition for Thalomid and Revlimid.

488. Prices for Thalomid and Revlimid have been and will continue to be inflated as a direct and foreseeable result of Celgene's anticompetitive conduct. The inflated prices that Plaintiffs' Assignors have paid and will continue to pay are traceable to, and the foreseeable result of, the overcharges by Celgene.

XIII. TOLLING OF THE STATUTE OF LIMITATIONS

1. Class Action Tolling

489. The claims asserted in this Complaint have been tolled as a matter of law by the pendency of various class actions, as to which Plaintiffs' Assignors were putative class members, alleging antitrust violations related to the actions by Defendants concerning Thalomid and Revlimid.[144]

2. Fraudulent Concealment Tolling

490. The claims asserted in this Complaint have been tolled as a matter of law as Defendants took affirmative steps to conceal the wrongful conduct alleged herein including, but not limited to, concealing their invalid patents through the use of sham citizen petitions and wholly improper patent litigation against generic manufacturers, *inter alia*.

3. Discovery Rule Tolling

491. Plaintiffs' Assignors had no way of knowing about Defendants' schemes alleged herein. Within the applicable statutes of limitation, Plaintiffs' Assignors could not have discovered through the exercise of reasonable diligence that Defendants were concealing the conduct complained of herein. Plaintiffs' Assignors did not discover, and did not know of, facts that would have caused a reasonable person to suspect, that the Defendants were engaged in the schemes alleged herein, nor would a reasonable diligent investigation have disclosed the true facts.

[144] *See, inter alia, International Union of Bricklayers and Allied Craft Workers Local 1 Health Fund v. Celgene Corporation*, Case no. 2:14-cv-06997 (D.N.J., November 7, 2014). Further, Plaintiffs timely excluded themselves from the certified settlement class of end payor plaintiffs.

4. Continuing Violation Doctrine

492. This Complaint alleges a continuing course of conduct (including conduct within the limitations periods), and Defendants' unlawful conduct has inflicted continuing and accumulating harm within the applicable statutes of limitations. Thus, Plaintiffs can recover for damages that they suffered during any applicable limitations period.

XIV. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
For Violations of Section 2 of the Sherman Act

493. Plaintiffs re-allege and incorporate by reference paragraphs 1-492 of this Complaint as though set forth at length herein.

494. At all relevant times, Celgene knowingly and willfully engaged in a course of conduct designed to prevent generic manufacturers from entering the market, and unlawfully extend its monopoly power. This course of conduct included refusing to sell or otherwise provide samples of Revlimid and Thalomid to generic manufacturers, fraudulently procuring the Distribution Methods Patents and the '886 Patent, improperly listing those patents in the Orange Book, and improperly filing and prosecuting patent infringement actions against generic manufacturers seeking to compete. Celgene's conduct was designed to indefinitely delay the introduction of generic formulations of Revlimid and Thalomid into the market and was in violation of Section 2 of the Sherman Act.

495. Celgene intentionally and improperly maintained its monopoly power with respect to Revlimid and Thalomid in violation of Section 2 of the Sherman Act, 15. U.S.C. § 2. Celgene's monopoly power was maintained through exclusionary tactics, and not from growth or development resulting from a superior product, business acumen, or historic accident. Because of this unlawful maintenance of monopoly power, Plaintiffs' Assignors paid artificially inflated process for Thalomid and Revlimid.

496. Plaintiffs' Assignors have been injured in their business and property by reason of Celgene's antitrust violations. Their injury consists of having paid and continuing to pay higher prices for Revlimid and Thalomid from at least 2010 to the present, including by assignment from their subsidiaries that purchased, and continue to purchase, Revlimid and Thalomid directly from Celgene, than they would have paid in the absence of Celgene's violations. Such overcharges are the type of injury the antitrust laws were designed to prevent and flows from that which makes Celgene's acts unlawful.

497. Even after generic competition begins, Plaintiffs' Assignors will continue to pay supracompetitive prices for generic versions of Revlimid and Thalomid until the market achieves equilibrium.

498. Plaintiffs' Assignors seek treble damages under Section 4 of the Clayton Act, 15 U.S.C. § 15, for their subsidiaries' direct purchases from Celgene of Revlimid and Thalomid from at least 2010 through the present, and for Plaintiffs' Assignors' subsidiaries overpayments for generic versions of Thalomid and Revlimid, if and when they belated became available.

SECOND CLAIM FOR RELIEF
Monopolization and Monopolistic Scheme under State Law

499. Plaintiffs re-allege and incorporate by reference paragraphs 1-492 of this Complaint as though set forth at length herein.

500. At all relevant times, Celgene possessed monopoly power in the defined relevant market since its NDAs for Thalomid and Revlimid were respectively approved. Celgene knowingly and willfully engaged in a course of exclusionary conduct designed to prevent generic manufacturers from entering the market and unlawfully extended its monopoly power.

501. Celgene intentionally extended its monopoly power in the relevant market through its anticompetitive and illegal scheme. Thus, Plaintiffs' Assignors paid artificially inflated prices

for their purchases of Thalomid and Revlimid. There is and was no non-pretextual justification for Celgene's anticompetitive actions.

502. As a direct and proximate result of Celgene's conduct, as alleged herein, Plaintiffs' Assignors were injured.

503. By engaging in the foregoing conduct, Celgene has intentionally and wrongfully maintained monopoly power in the relevant market in violation of the following state laws:

a. Cal. Bus. & Prof. Code §§ 17200, and California common law, with respect to purchases of Thalomid and Revlimid in California;

b. Conn. Gen. Stat. § 35-24, *et seq*., and Conn. Gen. Stat. § 42-110a, et seq., with respect to purchases of Thalomid and Revlimid in Connecticut;

c. Fla. Stat. §§ 501.201, *et seq*., with respect to purchases of Thalomid and Revlimid in Florida;

d. 740 Ill. Comp. Stat. 10/3, *et seq*., with respect to purchases of Thalomid and Revlimid in Illinois;

e. Mass. Gen. L. Ch. 93A, *et seq*., with respect to purchases of Thalomid and Revlimid in Massachusetts by Plaintiffs' Assignors, which paid substantially higher prices for Thalomid and Revlimid in actions and transactions occurring substantially within Massachusetts;

f. Mich. Comp. Laws Ann. §§ 445.773, *et seq*., with respect to purchases of Thalomid and Revlimid in Michigan;

g. N.Y. Gen. Bus. Law §§ 340, *et seq*., with respect to purchases of Thalomid and Revlimid in New York;

h. Ohio Rev. Code Ann. § 4165, *et seq*., with respect to purchases of Thalomid and Revlimid in Ohio;

i. 10 L.P.R.A. § 257, *et seq*., with respect to purchases of Thalomid and Revlimid in Puerto Rico;

j. R.I. Gen. Laws §§ 6-36-1, *et seq*., with respect to purchases of Thalomid and Revlimid in Rhode Island; and

k. Wis. Stat. § 133.03, *et seq*., with respect to purchases of Thalomid and Revlimid in Wisconsin by Plaintiffs' Assignors, in that the actions and transactions alleged herein substantially affected and continue to affect the people of Wisconsin, whereby Plaintiffs' Assignors paid substantially higher prices for Thalomid and Revlimid at Wisconsin pharmacies.

THIRD CLAIM FOR RELIEF
Attempted Monopolization Under State Law

504. Plaintiffs re-allege and incorporate by reference paragraphs 1-492 of this Complaint as though set forth at length herein.

505. Celgene, through its anticompetitive scheme, specifically intended to maintain monopoly power in the relevant market. It was Celgene's conscious objective to control prices and exclude competition in the relevant market.

506. The natural, intended, and foreseeable consequences of Celgene's anticompetitive scheme was to control prices and exclude competition in the relevant market, to the extent it did not succeed.

507. There is a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that Celgene will succeed in and achieve its goal of maintaining monopoly power in the relevant market.

508. As a direct and proximate result of Celgene's conduct, Plaintiffs' Assignors were harmed with respect to their purchases of Thalomid and Revlimid, as explained above.

509. By engaging in the foregoing conduct, Celgene has intentionally and wrongfully attempted to monopolize the relevant market in violation of the following state laws:

a. Cal. Bus. & Prof. Code §§ 17200, *et seq*., and California common law, with respect to purchases of Thalomid and Revlimid in California;

b. Conn. Gen. Stat. § 35-24, *et seq*., and Conn. Gen. Stat. § 42-110a, et seq., with respect to purchases of Thalomid and Revlimid in Connecticut;

c. Fla. Stat. §§ 501.201, *et seq*., with respect to purchases of Thalomid and Revlimid in Florida;

d. 740 Ill. Comp. Stat. 10/3, *et seq*., with respect to purchases of Thalomid and Revlimid in Illinois;

e. Mass. Gen. L. Ch. 93A, *et seq*., with respect to purchases of Thalomid and Revlimid in Massachusetts by Plaintiffs' Assignors, which paid substantially higher prices for Thalomid and Revlimid in actions and transactions occurring substantially within Massachusetts;

f. Mich. Comp. Laws Ann. §§ 445.773, *et seq*., with respect to purchases of Thalomid and Revlimid in Michigan;

g. N.Y. Gen. Bus. Law §§ 340, *et seq*., with respect to purchases of Thalomid and Revlimid in New York;

h. Ohio Rev. Code Ann. § 4165, *et seq*., with respect to purchases of Thalomid and Revlimid in Ohio;

i. 10 L.P.R.A. § 257, *et seq*., with respect to purchases of Thalomid and Revlimid in Puerto Rico;

j. R.I. Gen. Laws §§ 6-36-1, *et seq*., with respect to purchases of Thalomid and Revlimid in Rhode Island; and

k. Wis. Stat. § 133.03, *et seq*., with respect to purchases of Thalomid and Revlimid in Wisconsin by Plaintiffs' Assignors, in that the actions and transactions alleged herein substantially affected and continue to affect the people of Wisconsin, whereby Plaintiffs' Assignors paid substantially higher prices for Thalomid and Revlimid at Wisconsin pharmacies.

FOURTH CLAIM FOR RELIEF
Unfair and Deceptive Trade Practices Under State Law

510. Plaintiffs re-allege and incorporate by reference paragraphs 1-492 of this Complaint as though set forth at length herein.

511. Celgene engaged in unfair competition or unfair, unconscionable, deceptive, or fraudulent acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Celgene's anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiffs' Assignors were deprived of the opportunity to purchase generic versions of Thalomid and Revlimid and forced to pay artificially inflated prices for these drugs.

512. There was and is a gross disparity between the price that Plaintiffs' Assignors paid and continue to pay for their direct and indirect purchases of Thalomid and Revlimid and the value received, given that a much cheaper substitute generic product should be available, and prices for Thalomid and Revlimid should be much lower, but for Celgene's unlawful scheme.

513. By engaging in the foregoing conduct, Celgene has engaged in unfair competition or deceptive acts and practices in violation of the following state laws:

a. Cal. Bus. Code §§ 16700, *et seq*., and Cal. Bus. Code §§ 17200, et seq., with respect to purchases of Thalomid and Revlimid in California;

b. Conn. Gen. Stat. § 35-24, et seq., and Conn. Gen. Stat. § 42-110a, et seq., with respect to purchases of Thalomid and Revlimid in Connecticut;

c. Fla. Stat. §§ 501.201, *et seq*., with respect to purchases of Thalomid and Revlimid in Florida;

d. 815 Ill. Comp. Stat §§ 505/1, *et seq*., with respect to purchases of Thalomid and Revlimid in Illinois;

e. Mass. Gen. L. Ch. 93A, *et seq*., with respect to purchases of Thalomid and Revlimid in Massachusetts;

f. Mich. Stat. §§ 445.901, *et seq*., with respect to purchases of Thalomid and Revlimid in Michigan;

g. N.Y. Gen. Bus. Law §§ 349, *et seq*., with respect to purchases of Thalomid and Revlimid in New York;

h. Ohio Rev. Code Ann. § 4165, *et seq*., with respect to purchases of Thalomid and Revlimid in Ohio;

i. 10 L.P.R.A. § 251, *et seq*., with respect to purchases of Thalomid and Revlimid in Puerto Rico; and

j. Wis. Stat. § 100.18, Wis. Stat. § 100.20, *et seq*., with respect to purchases of Thalomid and Revlimid in Wisconsin by Plaintiffs' Assignors.

FIFTH CLAIM FOR RELIEF
Unjust Enrichment Under State Law

514. Plaintiffs re-allege and incorporate by reference paragraphs 1-492 of this Complaint as though set forth at length herein.

515. Celgene has benefitted from monopoly profits on the sale of Thalomid and Revlimid resulting from the unlawful and inequitable acts alleged in this Complaint.

516. Celgene's financial benefit resulting from its unlawful and inequitable acts is traceable to overpayments for direct and indirect purchases of Thalomid and Revlimid by Plaintiffs' Assignors.

517. Plaintiffs' Assignors have conferred upon Celgene an economic benefit, i.e., profits from unlawful overcharges and monopoly profits, to the economic detriment of Plaintiffs' Assignors.

518. It would be futile for Plaintiffs' Assignors to seek a remedy from any party with whom they have privity of contract with for its direct or indirect purchases of Thalomid and Revlimid.

519. It would be futile for Plaintiffs' Assignors to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which Plaintiffs' Assignors purchased Thalomid and Revlimid, as they are not liable and would not compensate Plaintiffs' Assignors for unlawful conduct caused by Celgene.

520. The economic benefit of overcharges and monopoly profits derived by Celgene through charging supracompetitive and artificially inflated prices for Thalomid and Revlimid is a direct and proximate result of Celgene's unlawful conduct.

521. The economic benefits derived by Celgene rightfully belong to Plaintiffs' Assignors, as they paid anticompetitive and monopolistic prices beginning in at least 2010 and continuing through the present, and they will continue to do so until the effects of Celgene's illegal and anticompetitive conduct cease.

522. It would be inequitable under unjust enrichment principles under the law of the District of Columbia and the laws of all states and territories in the United States, except Ohio and Indiana, for Celgene to be permitted to retain any of the overcharges for Revlimid and Thalomid derived from Celgene's unfair and unconscionable methods, acts, and trade practices alleged in this Complaint.

523. Celgene is aware of and appreciates the benefits bestowed upon it by Plaintiffs' Assignors.

524. Celgene should be compelled to disgorge in a common fund for the benefit of Plaintiffs all unlawful or inequitable proceeds it received.

525. A constructive trust should be imposed upon all unlawful or inequitable sums received by Celgene traceable to Plaintiffs' Assignors.

SIXTH CLAIM FOR RELIEF
Declaratory and Injunctive Relief Under Section 16 of the Clayton Act for Celgene's Violations of Section 2 of the Sherman Act

526. Plaintiffs re-allege and incorporate by reference paragraphs 1-492 of this Complaint as though set forth at length herein.

527. Celgene knowingly, intentionally, and cooperatively engaged in an anticompetitive scheme designed to delay and block entry of AB-rated generic equivalents of Thalomid and Revlimid. Celgene injured Plaintiffs' Assignors through this conduct.

528. Had manufacturers of generic Revlimid and generic Thalomid entered the market and lawfully competed with Celgene, Plaintiffs' Assignors would have substituted lower-priced generic Revlimid and generic Thalomid for the higher-priced brand-named drugs for most of their purchases.

529. Plaintiffs' Assignors have suffered harm and will continue to suffer harm in the future as a result of paying higher prices for Revlimid and Thalomid than they would have absent Celgene's continuing anticompetitive conduct.

530. Plaintiffs' Assignors' allegations described herein and in Claims I through V comprise violations of Section 2 of the Sherman Act, as well as state laws.

531. Plaintiffs' Assignors have overpaid for substantial amounts of Revlimid and Thalomid between at least 2010 and the present.

532. Plaintiffs' Assignors seek a declaratory judgment under Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201(a) ruling that Celgene's conduct violates Section 2 of the Sherman Act.

533. Plaintiffs' Assignors also seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15. U.S.C. § 26, and other applicable law, to correct for the anticompetitive market effects caused by Celgene's unlawful conduct and other relief to assure that similar anticompetitive conduct does not occur.

534. Plaintiffs' Assignors have no adequate alternative form of relief in the United States for their overpayment for Revlimid and Thalomid purchased indirectly in the states that do not provide damages remedies to indirect purchases injured by Celgene's anticompetitive conduct.

XV. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

1. Awarding Plaintiffs actual, consequential, compensatory, statutory, treble, punitive, and/or other damages, in an amount to be proven at trial, including pre- and post-judgment interest at the statutory rates;

2. Awarding Plaintiffs equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' unjust enrichment;

3. Declaring the acts alleged herein to be unlawful under the state statutes set forth above, and the common law of unjust enrichment of the states and territories set forth above and permanently enjoining Defendants from continuing their unlawful conduct;

4. Permanently enjoining Defendants pursuant to Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26, from continuing their unlawful conduct;

5. Declaring the acts alleged herein to be unlawful under the state statutes set forth above, and the common law of unjust enrichment of the states and territories set forth above;

6. Awarding Plaintiffs their reasonable costs and expenses, including attorneys' fees; and

7. Awarding such other legal or equitable relief as the Court deems just and proper.

XVI. JURY DEMAND

Plaintiffs demand a jury trial on all claims so triable under Fed. R. Civ. Proc. 38.

Dated: December 10, 2021

Respectfully submitted,

SANTOMASSIMO DAVIS LLP

By: */s/ Antony J. Davis*

Anthony J. Davis
Brian E. Moffitt
Attorneys for Plaintiffs
One Gatehall Drive, Suite 100
Parsippany, NJ 07054
201-712-1616
adavis@ogcsolutions.com
bmoffitt@ogcsolutions.com

Robert Strongarone (Fla. Bar No. 118931)
(*pro hac vice* forthcoming)
John W. Cleary (Fla. Bar No. 118137)
(*pro hac vice* forthcoming)
Aida M. Landa (Fla. Bar No. 0136451)
(*pro hac vice* forthcoming)
Attorneys for Plaintiffs
MSP RECOVERY LAW FIRM
2701 South Le Jeune Road
Coral Gables, Florida 33134
(305) 614-2222
strongarone@msprecoverylawfirm.com
alanda@msprecoverylawfirm.com
jcleary@msprecoverylawfirm.com
serve@msprecoverylawfirm.com
Shereef H. Akeel (MI Bar No. P54345)
(*pro hac vice* forthcoming)
Adam Akeel (MI Bar No. P81328)
(*pro hac vice* forthcoming)
Daniel W. Cermak (MI Bar No. 84460)
(*pro hac vice* forthcoming)
Attorneys for Plaintiffs

AKEEL & VALENTINE, PLC
888 West Big Beaver Road, Suite. 420
Troy, Michigan 48084
(248) 269-9595
shereef@akeelvalentine.com
adam@akeelvalentine.com
daniel@akeelvalentine.com

Eduardo Bertran, Fla. Bar. No. 94087
(*pro hac vice* forthcoming)
Attorney for Plaintiffs
ARMAS BERTRAN ZINCONE
4960 SW 72nd Avenue, Suite 206
Miami, Florida 33155
Phone: (305) 661-2021
ebertran@armaslaw.com

Appendix

Plaintiff MSPRC's Assignment to Demonstrate Standing

1. Certain series of MSPRC executed irrevocable assignments of any and all rights to recover payments made on behalf of their Assignors' Enrollees and health plan members. These assignments authorize the designated series, and in turn MSPRC through its LLC Agreement, to pursue and enforce all legal rights of recovery and reimbursement for health care services and benefits. MSPRC alleges the below assignment to demonstrate standing.

2. On May 12, 2017**, SummaCare, Inc. ("SMCR")** irrevocably assigned to MSP Recovery, LLC all its rights to recover against any liable third party (including Defendants) for payments made on behalf of its Enrollees ("SMCR Assignment"). Specifically, the SMCR Assignment states the following:

> [SMCR] hereby irrevocably assigns, transfers, conveys, sets over and delivers to MSP Recovery, and any of its successors and assigns, any and all of [SMCR]'s right, title, ownership and interests in and to all Claims existing on the date hereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies for [SMCR] that [SMCR] had, may have had, or has asserted against any party in connection with the Claims and all rights and claims against primary payers and/or third parties that may be liable to [SMCR] arising from or relating to the Claims, including claims under consumer protection statutes and laws, and all information relating thereto, all of which shall constitute the "Assigned Claims[.]"

SMCR Assignment at § 4.1.

3. On June 12, 2017, MSP Recovery, LLC irrevocably assigned all rights acquired under the SMCR Assignment to Series 16-11-509, a designated series of MSPRC ("Series 16-11-509 Assignment"):

> Assignor … irrevocably assigns, sells, transfers, conveys, sets over and delivers to Assignee and its successors and assigns, any and all of Assignor's right, title, ownership and interest in and to the [Assigned Claims] (and all proceeds and products thereof) as such terms are defined in the [SMCR Assignment.]

Series 16-11-509 Assignment at p.1.

4. SummaCare, Inc. consented to, acknowledged, approved, and ratified the Series 16-11-509 Assignment, which is memorialized in a letter dated September 5, 2018.

5. Consideration was given between each party in executing the SMCR Assignment and the Series 16-11-509 Assignment.

Plaintiff MSPA's Assignment Demonstrating Standing

1. MSPA was irrevocably assigned any and all rights to recover payments made on behalf of its Assignors' Enrollees and health plan members. These assignments authorize MSPA to pursue and enforce all legal rights of recovery and reimbursement for health care services and benefits. MSPA alleges the below assignment to demonstrate standing.

2. On December 16, 2014, **Interamerican Medical Center Group, LLC ("IMC")** irrevocably assigned to MSP Recovery, LLC all of its rights to recover against any liable third party (including Defendants) for payments made on behalf of its Enrollees ("IMC Assignment"). Specifically, the IMC Assignment, states the following:

> By way of this Agreement, [IMC] appoints, directs, and, otherwise, irrevocably assigns all of [IMC's] rights as it pertains to the rights pursuant to any plan, State or Federal statute(s) whatsoever directly and/or indirectly for any of its members and/or plan participants, and/or rights pursuant to any agreement[.]

IMC Assignment at § 1.1.

3. On February 20, 2015, MSP Recovery, LLC irrevocably assigned all rights acquired under the IMC Assignment to MSPA ("MSPA Assignment 3"):

> Assignor hereby irrevocably assigns, transfers, conveys, sets over, and delivers to Assignee or its assigns any and all of Assignor's right, title, ownership and interest in and all rights and entitlements, that Assignor has, may have had, or has asserted against third parties from or relating to the Claims [assigned pursuant to the IMC Assignment].

MSPA Assignment 3 at p. 1.

4. IMC consented to, acknowledged, approved, and ratified the MSPA Assignment 3.

5. Consideration was given between each party in executing the IMC Assignment and the MSPA Assignment 3.

Plaintiff MAO-MSO's Assignment Demonstrating Standing

1. MAO-MSO has been irrevocably assigned any and all rights to recover payments made on behalf of its Assignors' Enrollees and health plan members. These assignments authorize MAO-MSO to pursue and enforce all legal rights of recovery and reimbursement for health care services and benefits. MAO-MSO alleges the below assignment to demonstrate standing.

2. On May 3, 2016, **Preferred Medical Plan, Inc.** ("PMPI"), irrevocably assigned all its rights and claims to recover against any liable third party (including Defendants) for payments made on behalf of its Enrollees to MSP Recovery, LLC ("PMPI Assignment"). Specifically, the PMPI Assignment states:

> Client hereby irrevocably assigns, transfers, conveys, sets over and delivers to MSP Recovery, and any of its successors and assigns, any and all of Client's right, title, ownership and interest in and to all Claims existing on the date hereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recovery monies for Client that Client had, may have had, or has asserted against any party in connection with the Claims and all rights and claims against primary payers and/or third parties that may be liable to Client arising from or relating to the Claims, including claims under consumer protection statutes and laws, and all information relating thereto, all of which shall constitute the "Assignees Claims", as also specified in Section 1.1. The transfer, grant, right, or assignment of any and all of Client's right, title, ownership, interest and entitlements in and to the Assigned Claims shall remain the confidential and exclusive property of MSP Recovery or its assigns. The Assignment is intended to encompass and does hereby relate to any irrecoverable assignment in law and/or in equity. The Assignment shall be complete and irrevocable.

3. On August 8, 2016, MSP Recovery, LLC entered into an assignment agreement with MAO-MSO Recovery II LLC, Series PMPI, a segregated series of MSP Recovery Delaware LLC, whereby it irrevocably assigned its right to recover payments pursuant to state and federal

as previously assigned from PMPI. Specifically, Section 1.1 of the agreement states that:

> [a]ssignor hereby irrevocably assigns, sells, transfers, conveys, sets over and delivers to Assignee and its successors and assigns, all of Assignor's right, title, ownership and interest in and to all Assigned Claims, plus all proceeds, products and distributions of any kind, and proceeds of proceeds, in respect thereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies that Assignor had, may have had, or has asserted against any party in connection with the Assigned Claims, and all rights and claims against primary payers and/or third parties that may be liable to Assignor arising from or relating to the Assigned Claims, including claims under consumer protection statutes and laws, and all information relating thereto, all of which shall constitute the "Assigned Claims".

4. Consideration was given between each party in executing these assignment agreements.

Plaintiff Series 44's Assignment Demonstrating Standing

1. Certain series of Series 44 executed irrevocable assignments of any and all rights to recover payments made on behalf of their Assignors' Enrollees and health plan members. These assignments authorize the designated series, and in turn Series 44 through its LLC Operating Agreement, to pursue and enforce all legal rights of recovery and reimbursement for health care services and benefits. Series 44 alleges the assignments below to demonstrate standing.

2. Effective April 28, 2016, **Health First Health Plans, Inc. ("HFAP")** irrevocably assigned to MSP Recovery, LLC all rights under the to recover against any liable third party (including Defendants) for payments made on behalf of its Enrollees ("HFAP Assignment"). The HFAP Assignment expressly provides in pertinent part:

> Client hereby irrevocably assigns, transfers, conveys, sets over and delivers to MSP Recovery, and any of its successors and assigns, any and all of Client's right, title, ownership and interest in and to all Claims existing on the date hereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies for Client that Client had, may have had, or has asserted against any party in connection with the Claims and all rights and claims against primary payers and/or third parties that may be liable to Client arising from or relating to the Claims, including claims under consumer

> protection statutes and laws, and all information relating thereto, all of which shall constitute the "Assigned Claims".
>
> …
>
> The transfer, grant, right, or assignment of any and all of Client's right, title, ownership, interest and entitlements in and to the Assigned Claims shall remain the confidential and exclusive property of MSP Recovery or its assigns. This assignment is irrevocable and absolute.

HFAP Assignment at § 4.1.

3. Effective June 12, 2017, MSP Recovery, LLC assigned all rights acquired under the HFAP Assignment to Series 16-05-456, a designated series of MSPRC ("Series 16-05-456 Assignment). The Series 16-05-456 Assignment states:

> [T]he undersigned Assignor … irrevocably assigns, sells, transfers, conveys, sets over and delivers to Assignee and its successors and assigns, any and all of Assignor's right, title, ownership and interest in and to the Claims and Assigned Claims, (and all proceeds and products thereof, including any related assigned assets and assigned documents) as such terms are defined or contained in that certain (1) Assignment and (2) Addendum to the Recovery Agreement and Assignment Addendum, both given and effective April 28, 2016 and executed on June 1, 2018, by and between Health First Health Plans, Inc., a Florida corporation and Medicare Advantage Organization and party to contract number H1099 with The Centers for Medicare & Medicaid Services, as the "Client" and health plan assignor, and [MSP Recovery], a Florida limited liability company (the "Assignment"); irrespective of when the claims were vested in Client, inclusive of any and all claim(s), causes of actions, proceeds, products and distributions of any kind, and proceeds of proceeds, in respect thereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies that Assignor had, may have had, or has asserted against any party pursuant to the Assignment from the Client, including claims under consumer protection statutes and laws, any and all rights and claims against primary payers and/or third parties that may be liable to Client arising from or relating to the Claims and all information relating thereto.

Series 16-05-456 Assignment at p. 1.

4. On October 22, 2020, Series 16-05-456 irrevocably assigned all the rights it acquired from MSP Recovery, LLC to Series 44-20-456, a designated series of Series 44 ("Series 44-20-456 Assignment):

> Assignor . . . hereby irrevocably assigns, transfers, conveys, sets over, and delivers to [Series 44-20-456] and its successors and assigns, (i) any and all of Assignor's right, title, ownership, and interest in and to the [claims], as well as (ii) the "Claims" and "Assigned Claims", and all proceeds and products thereof (collectively the "Assigned Claims") as such terms are defined in the Agreements.

Series 44-20-456 Assignment at p. 1.

5. Consideration was given between each in executing the HFAP Assignment, the Series 16-05-456 Assignment, and the Series 44-20-456 Assignment.

Plaintiff Claims PROV's Assignment Demonstrating Standing

1. Certain series of Claims PROV executed irrevocable assignments of any and all rights to recover payments made on behalf of their Assignors' Enrollees and health plan members. These assignments authorize the designated series, and in turn Claims PROV through its LLC Operating Agreement, to pursue and enforce all legal rights of recovery and reimbursement for health care services and benefits. Claims PROV alleges the assignments below to demonstrate standing.

2. On February 3, 2021, **Pura Vida Medical Center, LLC** ("VIDA") irrevocably assigned all its rights and claims to recovery against any liable entity (including defendants) for payments made on behalf of its Enrollees to Series 20-06-1374, a designated series of MSP Recovery Claims PROV, Series LLC. Specifically, the VIDA Assignment, states the following:

> [Assignor] irrevocably assigns, sells, transfers, conveys, sets over and delivers to Assignee, and any of its successors and assigns, any and all of Assignor's right, title, ownership and interest in and to all of Assignor's Claims existing on the date hereof, and rights arising from and related to the claims data transferred to Assignee (or its affiliates or service providers, including MSP Recovery), these Claims encompassing the "Assigned Claims." This assignment is irrevocable and absolute, and is broad with respect to recovery efforts and is not limited to any particular recovery strategy regarding reimbursement or recovery efforts.

3. Consideration was given between the parties in executing this assignment.

Plaintiff Claims CAID's Assignment Demonstrating Standing

1. Certain series of Claims CAID executed irrevocable assignments of any and all rights to recover payments made on behalf of their Assignors' Enrollees and health plan members. These assignments authorize the designated series, and in turn Claims CAID through its LLC Operating Agreement, to pursue and enforce all legal rights of recovery and reimbursement for health care services and benefits. Claims CAID alleges the assignments below to demonstrate standing.

2. On February 3, 2021, **Sal Health Group. LLC d/b/a Salubris** ("Salubris") irrevocably assigned all its rights and claims to recovery against any liable entity (including Defendants) for payments made on behalf of its Enrollees to Series 19-10-1128, a designated series of MSP Recovery Claims CAID, Series LLC ("Salubris Assignment"). Specifically, the Salubris Assignment, states the following:

> [Assignor] irrevocably assigns, transfers, conveys, sets over and delivers to Assignee, and any of its designated series, successors and assigns, any and all of Assignor's right, title, ownership, and interest in and to all of Assignor's Claims and rights arising from and related to the claims data transferred to Assignee (or its affiliates or services providers, including MSP Recovery, LLC) for the period encompassing dates of services from June 1, 2014 and continuing up to, including and through June 30, 2020, these Claims encompassing the "Assigned Claims." The assignment of the Assigned Claims set forth herein is irrevocable and absolute and is broad with respect to recovery efforts and is not limited to any particular recovery strategy regarding reimbursement or recovery efforts.

3. Consideration was given between the parties in executing this assignment.